HIV Screening and Antiretroviral Treatment

OBJECTIVE

The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for the screening and antiretroviral treatment of HIV/AIDS. Initiation of antiretroviral therapy (ART) during acute infection may have a number of beneficial clinical outcomes, including improved preservation of immunologic function, significantly reduced time to viral suppression, and reduction of the viral reservoir, which could be important for cure strategies. The public health benefit of early initiation of ART is well documented, with a significant reduction of HIV transmission among virally suppressed individuals. The CPG also discusses the medical and behavioral health implications of living with HIV/AIDS. In addition, the CPG outlines the organizations that WellCare aligns with regarding HIV/AIDS and relevant Measureable Health Outcomes.

OVERVIEW

Infection with human immunodeficiency virus (HIV) produces a spectrum of disease that progresses from a clinically latent or asymptomatic state to acquired immunodeficiency syndrome (AIDS) as a late manifestation. The pace of disease progression varies. In untreated patients, the time between infection with HIV and the development of AIDS ranges from a few months to as long as 17 years (median: 10 years). The majority of adults and adolescents infected with HIV remain symptom-free for extended periods, but viral replication is active during all stages of infection and increases substantially as the immune system deteriorates. In the absence of treatment, AIDS will develop eventually in nearly all HIV-infected persons. Proper management of HIV infection involves a complex array of behavioral, psychosocial, and medical services. Services might not be available in STD-treatment facilities. Therefore, referral to a health-care provider or facility experienced in caring for HIV-infected patients is advised. Providers working in STD-treatment facilities should be knowledgeable about the options for referral available in their communities. While receiving care in STD-treatment facilities, HIV-infected patients should be educated about HIV infection and options for support services and HIV care. A person is considered at increased risk for HIV infection, and should be offered HIV testing, if he or she reports 1 or more individual risk factors or receives health care in a high-prevalence or high-risk clinical setting. Individual risk is assessed through a careful patient history. Those at increased risk include:

- Men who have had sex with men after 1975;
- Men and women have unprotected sex with multiple partners;
- Past and present injection drug users;
- Men and women who exchange sex for money or drugs or have sex partners who do;
- Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;
- Persons being treated for sexually transmitted diseases (STDs); and,

NOTE: Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk, since the group is likely to include individuals not willing to disclose high risk behaviors.

An estimated 1.1 million people in the United States were living with HIV at the end of 2014, the most recent year for which this information is available. Of those people, about 15%, or 1 in 7, did not know they were infected. Young people were the most likely to be unaware of their infection. Among people aged 13-24, an estimated 51% (31,300) of those living with HIV at the end of 2013 didn’t know. Among those with AIDS, 18,303 people were diagnosed with AIDS in 2015. Since the epidemic began in the early 1980s, 1,216,917 people have been diagnosed with AIDS. In 2014,
there were 12,333 deaths (due to any cause) of people with diagnosed HIV infection ever classified as AIDS, and 6,721 deaths were attributed directly to HIV. Highlights from the CDC are below – the full report can be accessed here.²

- Gay and bisexual men are most affected by HIV. In 2015, they accounted for 82% (26,375) of HIV diagnoses among males and 67% of all diagnoses. Black/African American gay and bisexual men accounted for the largest number of HIV diagnoses (10,315), followed by White gay and bisexual men (7,570).
- From 2005 to 2014, diagnoses among White gay and bisexual men dropped steadily by 18% overall. However, among Hispanic/Latino gay and bisexual men, diagnoses increased by 24%.
- Among Black / African American gay and bisexual men, diagnoses are steady with an increase of < 1% in the past 5 years. Young African American gay and bisexual men (aged 13 to 24) experienced an 87% increase in diagnoses; since 2010 diagnoses have declined 2%.
- Heterosexuals contact accounted for 24% (9,339) of HIV diagnoses. Women accounted for 19% (7,402) of HIV diagnoses. Diagnoses among women were also contributed to injection drug use (IDU) (13%).
- Injection drug use accounts for 6% (2,392) of HIV diagnoses; an additional 3% (1,202) of cases are categorized as to male-to-male sexual contact and IDU.
- From 2005 to 2014, diagnoses among all women declined 40%, and among African American women, diagnoses declined 42%. Among all heterosexuals, diagnoses declined 35%, and among people who inject drugs, diagnoses declined 63%.
- By age group of persons diagnosed with HIV in the United States in 2015:
  - 37% (14,594) were aged 20-29
  - 24% (9,631) were aged 30-39
  - 17% (6,720) were aged 40-49
  - 12% (4,870) were aged 50-59
  - 5% (1,855) were aged 60 and over
  - 4% (1,723) were aged 13-19
- African Americans continue to experience the greatest burden of HIV compared to other races and ethnicities. Hispanics/Latinos are also disproportionately affected by HIV. In 2015, African Americans represented 12% of the US population and accounted for 45% (17,670) of HIV diagnoses. Hispanics/Latinos represented about 18% of the US population and accounted for 24% (9,290) of HIV diagnoses.

### Hierarchy of Support

**Guideline Hierarchy**

CPGs are updated annually or as necessary due to updates made to guidelines or recommendations by the United States Preventive Services Task Force (USPSTF), the American Congress of Obstetricians and Gynecologists (ACOG), AIDS Institute, and the International Antiretroviral Society USA (ISA-USA) Panel. When there are differing opinions noted by national organizations, WellCare will default to the member’s benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to screening and antiretroviral treatment of HIV/AIDS, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- United States Preventive Services Task Force (USPSTF), National Quality Strategy (NQS), Agency for Healthcare Research and Quality (AHRQ);
- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).

Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with the USPSTF, ACOG, AIDS Institute, and ISA-USA on the topic of screening and antiretroviral treatment of HIV/AIDS. Highlights from their respective publications are noted below.

### United States Preventive Services Task Force (USPSTF)

The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.¹

The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who...
are untested and whose HIV status is unknown.¹

**Benefits of Detection and Early Intervention.** The USPSTF found convincing evidence that identification and treatment of HIV infection is associated with a markedly reduced risk for progression to AIDS, AIDS-related events, and death in individuals with immunologically advanced disease (defined as a CD4 count <0.200 x 109 cells/L). Adequate evidence shows that initiating combined antiretroviral therapy (ART) earlier (that is, at CD4 counts between 0.200 and 0.500 x 109 cells/L)—when individuals are more likely to be asymptomatic and detected by screening rather than clinical presentation—is also associated with reduced risk for AIDS-related events or death. The USPSTF found convincing evidence that the use of ART is associated with a substantially decreased risk for transmission from HIV-positive persons to uninfected heterosexual partners. Convincing evidence also shows that identification and treatment of HIV-positive pregnant women dramatically reduces rates of mother-to-child transmission. The overall benefits of screening for HIV infection in adolescents, adults, and pregnant women are substantial.¹

**Harms of Detection and Early Intervention.** The USPSTF found convincing evidence that individual antiretroviral drugs, drug classes, and combinations are all associated with short-term adverse events; however, many of these events are transient or self-limited, and effective alternatives can often be found. Although the long-term use of certain antiretroviral drugs may be associated with increased risk for cardiovascular and other adverse events, the magnitude of risk seems to be small. The overall harms of screening for and treatment of HIV infection in adolescents, adults, and pregnant women are small.¹

The USPSTF is currently developing the following recommendations for publication in 2019:

- Human Immunodeficiency Virus (HIV) Infection in Non-pregnant Adolescents and Adults: Screening
- Human Immunodeficiency Virus (HIV) Infection in Pregnant Women: Screening
- Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis

Additional age-specific information can also be found in the following Preventive Health CPGs: Adolescent (HS-1051), Adult (HS-1018), Older Adult (HS: 1063), and Pediatric (HS-1019).

**AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)**

**Routine HIV Screening**

Recommendations for routine HIV screening from ACOG include the following:

- All females aged 13–64 years should be tested at least once in their lifetime; annually thereafter based on factors related to risk.
- Obstetrician–gynecologists should annually review patients’ risk factors and assess the need for retesting.
- Opt-out HIV screening should be performed.
- Obstetrician–gynecologists who use rapid HIV tests must be prepared to provide counseling to women who receive positive test results the same day that the specimen is collected.
- Women who are infected with HIV should receive or be referred for appropriate clinical and supportive care.

Prevention of transmission of the human immunodeficiency virus (HIV) from mother to fetus or newborn (vertical transmission) is a major goal in the care of pregnant women infected with HIV. Additional information is included below.

To read the full Committee Opinion on routine HIV screening, click [here].³

**Women of Color**

Most new cases of HIV/AIDS in the United State are among women of color (primarily African American and Hispanic women), usually from heterosexual partner with undisclosed risk factors for HIV infection. A combination of testing, education, and brief behavioral interventions can also reduce the rates and complications as outlined below:⁴

- Routine HIV screening for women aged 19–64 years is recommended by ACOG; targeted screening for women with risk factors outside of that age range (e.g., sexually active adolescents younger than 19 years) is also recommended. Opt-out HIV screening should be performed, in which the patient is notified that HIV testing will be performed as a routine part of gynecologic and obstetric care, unless the patient declines testing (as according to state laws and regulations).
In addition, ACOG presents the following additional approaches to reduce the rate of HIV infection in women of color:

- **Women whose confirmatory testing yields positive results and, therefore, are infected with HIV should receive or be referred for appropriate clinical and supportive care.** Early recognition allows initiation of optimal care and medication, when indicated, as well as education to prevent transmission.
- **Safe sex practices, especially consistent condom use, must be emphasized for all women, particularly for women of color.** Patients should be asked the reason they are not using condoms to assess whether the patient feels safe negotiating condom use (see Resources). Multiple studies have shown that behavioral interventions can increase rates of condom use, reduce risk-taking behavior, and decrease rates of acquisition of STIs. Most interventions are designed to be provided by nurses or peer educators and often are available through local health departments or community organizations.
- **Health care providers are urged to identify resources in their communities for training of office staff in risk reduction interventions for women of color or for referral of women to these programs.** A combination of testing, education, and brief behavioral interventions can help reduce the rate of HIV infection and its complications among women of color.

To read the full Committee Opinion on HIV/AIDS and women of color, click [here](#).

### Prenatal and Perinatal HIV Testing

Nearly 50,000 individuals become infected with HIV annually in the United States; approximately 150 of these new infections are infants infected by mother-to-child transmission. Mother-to-child transmission rates are reduced when antiretroviral medications are given to women with HIV during pregnancy and delivery and to their newborns in the first weeks of life. Early identification and treatment of all pregnant women with HIV is the best way to prevent neonatal infection and also improve women's health. ACOG guidelines include the following recommendations:

- All pregnant women should be screened for HIV infection as early as possible during each pregnancy using the opt-out approach where allowed.
- Repeat HIV testing in the third trimester is recommended for women in areas with high HIV incidence or prevalence and women known to be at risk of acquiring HIV infection.
- Women who were not tested earlier in pregnancy or whose HIV status is otherwise undocumented should be offered rapid screening on labor and delivery using the opt-out approach where allowed.
- If a rapid HIV test result in labor is reactive, antiretroviral prophylaxis should be immediately initiated while waiting for supplemental test results.
- If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for co-management.

The American Academy of Pediatrics (AAP) and ACOG strongly support efforts to further reduce the rate of perinatal transmission of HIV in the United States. In addition, they support the recommendation of the Institute of Medicine (IOM) for universal HIV testing with patient notification as a routine component of prenatal care. If a patient declines testing, it should be noted in the medical record. Counseling is also recommended as part of routine care, but not as a prerequisite for, and barrier to, prenatal HIV testing. The AAP and ACOG note that Providers should abide with the laws of their practicing state. To read the full statement, click [here](#).

### Scheduled Cesarean Delivery and the Prevention of Vertical Transmission of HIV Infection

Prevention of transmission of the human immunodeficiency virus (HIV) from mother to fetus or newborn (vertical transmission) is a major goal in the care of pregnant women infected with HIV. An important advance in this regard was the demonstration that treatment of the mother with zidovudine (ZDV) during pregnancy and labor and of the neonate for the first 6 weeks after birth could reduce the transmission rate from 25% to 8%. Highlights of the Opinion includes:

- Patients should be counseled that in the absence of antiretroviral therapy the risk of vertical transmission is approximately 25%. With ZDV therapy, the risk is reduced to 5–8%. When care includes both ZDV therapy and scheduled cesarean delivery, the risk is approximately 2%.
- Women infected with HIV, whose viral loads are greater than 1,000 copies per milliliter, should be counseled regarding the potential benefit of scheduled cesarean delivery to further reduce the risk of vertical transmission of HIV beyond that achievable with antiretroviral therapy alone.
- Patients should receive antiretroviral chemotherapy during pregnancy according to currently accepted
guidelines for adults. This should not be interrupted around the time of cesarean delivery. For those patients receiving ZDV, adequate levels of the drug in the blood should be achieved if the infusion is begun 3 hours preoperatively, according to the dosing schedule recommended by the CDC. Generally ACOG recommends that scheduled cesarean deliveries not be performed before 39 completed weeks of gestation. In women with HIV infection, however, delivery at 38 completed weeks of gestation is recommended to reduce the likelihood of onset of labor or rupture of membranes before delivery. To read the full Committee Opinion on scheduled cesarean delivery and the prevention of vertical transmission of HIV infection, click here.7

Gynecologic Care for Women and Adolescents With Human Immunodeficiency Virus8

In the United States, women account for 24% HIV cases. African American and Hispanic women combined account for 78% of HIV-infected women. In most women with HIV, the infection is diagnosed during the reproductive years. Key highlights of ACOG recommendations are noted below with respect to gynecological care for women with HIV/AIDS:

- Condom use should be encouraged to prevent transmission of HIV and acquisition of other STIs.
- Antiretroviral therapy, with the goal of achieving a fully suppressed HIV viral load, can decrease transmission to uninfected partners.
- Seronegative male partners of an HIV-infected woman should consider use of antiretroviral pre-exposure prophylaxis with a daily fixed dose of oral tenofovir disoproxil fumarate and emtricitabine.
- Copper IUD and levonorgestrel-releasing IUDs can be used by HIV-infected women.
- Annually screen for risk behaviors and referral for behavioral interventions (as applicable); more frequently if necessary, to reduce high-risk sexual and drug behaviors that can transmit HIV.
- Vaginal spermicides that contain nonoxynol-9 should be avoided due to an increase risk of HIV transmission.
- Hormonal contraception is generally considered safe for use, including those who use antiretroviral therapy.
- Depot medroxyprogesterone acetate can be prescribed to women with HIV because it is considered safe (MEC category 1) and effective for use and does not appear to have drug interactions with antiretroviral medications.
- Women < 30 years, if the initial cytology screening result is normal, the next cytology screening should be in 12 months. If the results of three consecutive annual cervical cytology screenings are normal, follow-up cervical cytology screening should be every 3 years. Co-testing (cervical cytology and HPV screening) is not recommended for HIV-infected women younger than 30 years.
- Women >30 years can be screened with cytology alone or co-testing. After women screened with cytology alone have had three consecutive annual test results that are normal, follow-up screening can be every 3 years. Women infected with HIV who have one negative co-test result (normal cytology and HPV negative) can have their next cervical cancer screening in 3 years.

To read the full Practice Bulletin and recommendations on gynecological care for females with HIV, click here.8

Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus.

Preexposure prophylaxis is defined as the administration of antiretroviral medications to individuals who are not infected with human immunodeficiency virus (HIV) and are at the highest risk of acquiring HIV infection. In combination with other proven HIV-prevention methods, preexposure prophylaxis may be a useful tool for women at the highest risk of HIV acquisition. Obstetrician–gynecologists involved in the care of women using preexposure prophylaxis must reinforce adherence to daily medication. Risk reduction for all women at risk of HIV infection should include counseling about testing, safe-sex practices (including condom use), and other behavioral interventions. Adherence to prescribed prophylaxis may be the most critical variable in preventing HIV infection with preexposure prophylaxis. To read the full Committee Opinion on pre-exposure prophylaxis for the prevention of HIV, click here.9

AIDS INSTITUTE

Highlights from the AIDS Institute publication Diagnosis and Management of Acute HIV Infection are noted below.

Recommendations for Initiating ART (updated September 2015)10

1. ART should be recommended for all patients with a diagnosis of HIV infection.
2. Clinicians should strongly recommend initiation of ART for patients who present with any of the following conditions that increase the urgency of starting ART:
• AIDS-defining condition
• Pregnancy
• Symptomatic from HIV, including any of the following: HIV-associated neurocognitive disorder (HAND), severe thrombocytopenia, HIV-associated nephropathy, and/or HIV-related malignancies
• Chronic hepatitis B or C infection
• Age 50 or older

3. Patients with seronegative partners should be counseled about the reduction of HIV transmission risk when effective ART is initiated; ART is strongly recommended in patients with seronegative partners.

4. Decisions to initiate ART should be individualized, particularly for the following populations: long-term non-progressors, elite controllers, or patients with potential barriers to adherence.

Additional recommendations published by the AIDS Institute include:10,11

• Evaluation and preparation for ART initiation includes each of the following essential components:
  o Discussion with the patient about risks and benefits of ART;
  o Assessment of patient readiness;
  o Identification and amelioration of factors that might interfere with successful adherence to treatment, including inadequate access to medication, inadequate supportive services, psychosocial factors, active substance use, or mental health disorder.

• Clinicians should refer patients for supportive services as necessary to address modifiable barriers to adherence. An ongoing plan for coordination of care should be established.

• Clinicians should involve patients in the decision-making process regarding initiation of ART. The patient should make the final decision of whether and when to initiate ART.

• When the decision to initiate treatment is made, ART should be prescribed and monitored by, or in consultation with, clinicians who have experience in managing ART.

• Obtain baseline HIV genotypic resistance testing, regardless of whether ART is being initiated.11
  When acute HIV infection is diagnosed in a person receiving pre-exposure prophylaxis (PrEP), a fully active ART regimen should be recommended in consultation with an experienced HIV care provider.11
  When acute HIV infection is diagnosed in a person receiving post-exposure prophylaxis (PEP), ART should be continued pending consultation with an experienced HIV care provider.11

**RNA Assay and Testing**

• A positive HIV RNA assay is a preliminary diagnosis of HIV; ART should be recommended while waiting for confirmatory testing.11
• If a diagnosis of acute infection is made on the basis of HIV RNA testing, initiation of ART should be recommended while awaiting serologic confirmation.11
• When pregnant women are diagnosed with acute infection by HIV RNA testing, clinicians should not wait for results of a confirmatory test to initiate ART; initiation of ART is strongly recommended for pregnant women.11

**Barriers and Deferring ART**10

In patients with advanced HIV (or AIDS), ART should be initiated even if barriers to adherence are present. In these cases, referrals to specialized adherence programs should be made for intensified adherence support.

Except in cases when initiation of treatment is urgent, clinicians should educate and prepare patients before initiating ART in those with potential barriers to adherence, including active alcohol or drug use; lack of insurance, transportation, or housing; depression; mistrust of medical providers; or a poor social support system.

Decisions to initiate ART in long-term non-progressors and elite controllers should be individualized.

Clinicians should consult with a provider experienced in the management of ART when considering whether to initiate
ART in long-term non-progressors and elite controllers.

NOTE: Long-term non-progressors demonstrate a lack of disease progression, marked by no symptoms and low viral loads in the absence of therapy during long-term follow-up. Most published studies of long-term non-progressors include 7-10 years of follow-up. Elite controllers suppress HIV to low but detectable levels (<50-75 copies/mL) for many years.

Initiating ART Following Acute Opportunistic Infections

Clinicians should recommend that patients beginning treatment for acute opportunistic infections (OIs) initiate ART within 2 weeks of OI diagnosis (see next recommendation for exceptions).

Clinicians should not immediately initiate ART in patients with tuberculous meningitis or cryptococcal meningitis.

Consultation with a clinician with experience in management of ART in the setting of acute OIs is recommended.

For all other manifestations of tuberculosis (TB), clinicians should initiate ART in HIV-infected patients as follows:
- For patients with CD4 counts ≥50 cells/mm³: as soon as they are tolerating anti-TB therapy and no later than 8-12 weeks after initiating anti-TB therapy.
- For patients with CD4 counts <50 cells/mm³: within 2 weeks of initiating anti-TB therapy.

Patient Adherence

NOTE: Last updated in July 2004; currently under revision by the AIDS Institute.

A team approach to achieving adherence should be used. Nurses, pharmacists, peer counselors, caseworkers, and others who work in outreach, evaluation, and support of adherence should be involved.

The clinician should assess treatment readiness prior to initiation of treatment, adherence readiness for subsequent regimens, and adherence at every clinical visit.

Interventions should be intensified in times of decreased adherence.

Information about patients’ beliefs and attitudes should be communicated with all members of the healthcare team so that each provider can consistently address treatment adherence issues within the context of the overall treatment plan.

If the patient is not fully committed to adhering to therapy, treatment should be delayed, and the clinician should continue to work on abating the patient’s concerns. Appropriate referrals should be provided for support groups, mental health, and drug treatment.

Potential barriers to adherence include:
- Communication difficulties that arise when the patient’s attitude about disease and therapy is different from that of the provider’s. Without open and nonjudgmental communication from the healthcare team, patients may not trust or may misunderstand the prescribed regimen.
- Language or literacy barriers.
- Unstable living situations (including limited or absent social support).
- Discomfort with disclosure of HIV status, which may become known when medications are taken.
- Inability to set long-term goals.
- Inadequate knowledge about disease and effectiveness of medications or healthy living, including a patient’s lack of belief in his/her ability to take medications regularly.
- Difficulty accessing adequate health care.
- Housing, food, lack of childcare, or other immediate life needs, which are viewed as more pressing than taking the medications regularly.

Strict adherence to ART is essential for maintaining treatment benefit and preventing the development of HIV resistance. Study results are clear on the importance of a high level of adherence for good virologic control. Adherence to >95% of PI doses has been correlated with sustained viral suppression in several studies. Good adherence frequently wanes over time, and patients may need significant support the longer the duration of therapy.

Patient Adherence Education

Strategies to encourage patients to adhere to treatment include:
To foster understanding of the importance of adherence, providers should present easy to understand information, consistent with the patient’s level of education, and free of medical jargon.

Allow sufficient time to fully educate the patient about the goals of treatment and the need for adherence, both before beginning treatment and frequently during therapy.

Provide literature and, if available, peer counselors should be enlisted to reinforce education efforts. Attention to language and use of culturally sensitive education materials are essential.

Adherence tools should be provided. Written schedules, pictures of medications, pillboxes, alarms, and pagers may help patients understand and remember medication schedules. The need for greater adherence support (e.g., support groups, home visits, day treatment programs) should be assessed.

Review the viral load response to ART in graphic form with the patient to reinforce the efficacy of therapy.

Advise the patient of events that may interrupt treatment and interfere with patient access to medications (e.g., travel, pharmacy delays in restocking medications, manufacturer shortages, loss of medication, or incarceration). In addition, the patient should be counseled to notify his/her clinician for discussion of alternative options as soon as the patient foresees the occurrence of an interruption.

Patients should be cautioned that if one (or more) drug in their ART regimen is not available for more than several days, all antiretroviral agents should be stopped until the entire ART regimen is again available to avoid the emergence of resistance while using a less suppressive regimen. This issue is of greatest concern when the antiretroviral agent in question is one to which a single point mutation confers a great degree of resistance (e.g., lamivudine and NNRTIs), which appears rapidly in the absence of a fully suppressive regimen.

**Substance Use and Adherence**

Clinicians should help active substance users plan to decrease or stabilize their use in preparation for initiating ART. Discussion should include how patterns of substance use may affect adherence. Providers should work with other providers experienced with treating this group to encourage reduction in substance use. The link between reducing drug use and engaging in successful HIV treatment should be encouraged.

**Patient Monitoring**

Periodic laboratory tests are necessary to evaluate the response to ART and its potential related side effects. In the setting of ART failure, viral resistance assays should be used.

**Virologic and Immunologic Monitoring.** Quarterly CD4 count monitoring is no longer recommended for non-pregnant patients receiving ART who have consistently undetectable HIV RNA levels and CD4 counts >200 cells/mm3. Regular monitoring of HIV RNA levels remains the most accurate and meaningful measure of effective ART. The AIDS Institute recommends that clinicians should monitor HIV RNA levels and CD4 counts according to the recommended intervals noted in the full AIDS Institute publication. Follow-up visits should be scheduled more frequently as clinically necessary to address non-HIV-related conditions, secondary prevention, and issues that may affect adherence to ART or retention in care, such as substance use, mental health disorders, unstable housing, or need for supportive services.

**Key Point:** Quarterly HIV RNA monitoring remains appropriate for patients with a recent history of non-adherence, mental health disorders, substance use, homelessness, poor social support system, or other major medical conditions. Semiannual monitoring may be appropriate for patients with persistently undetectable HIV RNA and none of the above characteristics. Additional information is found in the full update including allergic reactions and monitoring side effects.

**HIV Resistance Assays**

The AIDS Institute recommends that clinicians should perform resistance testing under the following circumstances:

- At baseline, regardless of whether ART is being initiated (genotypic testing)
- In ART-naïve patients before initiation of ART (genotypic testing)
• In patients experiencing treatment failure or incomplete viral suppression while receiving ART (genotypic and/or phenotypic testing)

When resistance testing is indicated, it optimally should be performed while patients are either receiving therapy or have been off therapy for less than 1 year. Clinicians should consult with an expert to interpret the results of resistance assays because the results of resistance assays are often complex.

**Failure to Achieve Goals of Initial ART**

The AIDS Institute recommends that clinicians address adherence, obtain resistance assays, and consult with a provider with experience in HIV treatment before changing ART regimens that have failed. Clinicians should not change an ART regimen when there is incomplete but significant viral suppression (≥0.5 log reduction, or 3-fold, from baseline viral load value) compared with baseline and a more effective ART regimen cannot be constructed as a result of drug resistance or intolerance.

The goal of ART is to use a regimen that is well tolerated and that will promote maximal viral suppression and immune reconstitution. Failure to demonstrate a >1.5-log drop in viral load within 3 months of treatment and, more importantly, failure to achieve a viral load <50 copies/mL within 6 months (depending on baseline viral load) indicates unsuccessful ART. The initial ART regimen affords the best opportunity to attain maximal viral suppression. Currently, in clinic practice, only 60% to 70% of patients receiving initial ART will achieve sustained viral loads below the limits of detection by ultrasensitive assays. The reasons for this are complex. Low levels of detectable viremia should not be the sole determinant of treatment failure. Treatment failure is best defined by any one of the following:

- Failure of viral load to decrease from baseline
- Progressive increase in viral load after initial suppression
- Progressive decline of CD4 cell counts
- Progression of HIV disease

**Management of Treatment Interruption**

The AIDS Institute recommends that patients should be discouraged from stopping ART without first consulting with their clinician. When ART is interrupted, clinicians should inform patients of the potential increased risk of transmitting HIV. Risk-reduction counseling and prevention interventions should be intensified at this time. Before interrupting ART in patients receiving antiretroviral medications with prolonged half-lives, such as NNRTIs, clinicians should consult with a provider with experience in HIV treatment for guidance on how to avoid the emergence of resistance. In addition, clinicians should not interrupt lamivudine, emtricitabine, or tenofovir (or combination pills containing these drugs) in patients who are co-infected with chronic hepatitis B without implementing another HBV treatment option. Strategic treatment interruption (STI) is not recommended in the management of the HIV-infected patient. Some of the scenarios that could result from disrupting ART include:

- Serious adverse drug reactions (e.g., rashes, neuropathy, severe lipoatrophy or fat redistribution, severe nephrolithiasis)
- Lack of access to drugs due to poverty, incarceration, or lack of medical benefits
- Medical/surgical conditions requiring patients to avoid eating or drinking for a specified time period (e.g., pancreatitis, appendicitis)
- Poor adherence (e.g., lack of adherence may be sufficient cause for the clinician to stop treatment while further interventions and education attempts are undertaken)
- Minor drug side effects that mimic disease progression, making it necessary to temporarily interrupt therapy for clinical evaluation of signs and symptoms

In addition, patients may decide to stop therapy due to treatment fatigue, fear of toxicities (e.g., fat redistribution, cardiac disease), traveling overseas for an extended period, perceived ineffectiveness of medications, or pregnancy and fear of teratogenicity.

**Referral to Research Studies**

The AIDS Institute recommends that the referral of patients to research protocols should be 1) to provide treatment or diagnostic options that may be otherwise unavailable and that may enhance treatment outcome, and 2) to attempt to
answer a relevant research question. In addition, patients should be fully informed of any financial benefit their referral to a research study might have for the referring clinician. Patients should also be informed that research studies often require major commitments of time and effort in addition to potential unforeseeable risk. Finally, the clinician should provide assistance to patients who want to participate in research studies.

INTERNATIONAL ANTIRETROVIRAL SOCIETY USA PANEL

Highlights International Antiretroviral Society USA (ISA-USA) Panel recommendations on antiretroviral treatment of adult HIV infection are noted below. To read the ISA-USA recommendations as well as view tables on treatment regimens and alternatives, click here. The recommendations include the addition of a section on initial combination regimens for the antiretroviral-naive patient. The approval of 3 fixed-dose combination products containing tenofovir alafenamide (an oral prodrug of tenofovir) and emtricitabine (TAF/FTC) prompted several changes.\textsuperscript{12}

The Panel also focused on regimen switching and simplified the section to focus on switch strategies for virologically suppressed patients. A new section is also included on HIV-infected women; this section emphasizes ART for all HIV-infected patients, including all HIV-infected women. The Panel also stressed the importance of early treatment for HIV-infected women during pregnancy and continuation of ART after pregnancy. The section was updated to include new data on interactions between antiretroviral (ARV) drugs and hormonal contraceptives. The USA Panel also highlighted coinfection of HIV with Hepatitis B (HBV), Hepatitis C (HCV), and Tuberculosis (TB).\textsuperscript{12}

Monitoring

Readiness of the patient for treatment should be considered prior to initiating ART. ART should be recommended and offered regardless of CD4 cell count. The strength of the recommendation increases as the CD4 count decreases.\textsuperscript{2}

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<td>• Pregnant women</td>
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<td>• HIV-associated neuropathy</td>
<td>• During the acute phase of primary HIV infection, regardless of symptoms</td>
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Plasma HIV-1 RNA levels\(^\textsuperscript{8}\) should be monitored frequently when treatment is initiated or changed for virologic failure, until they decrease below detection limits\(^\textsuperscript{8}\) and regularly thereafter. Once the viral load is suppressed for a year and CD4 cell counts are stable at \(\geq 350/µL\), viral load and CD4 cell counts can be monitored at intervals of up to 6 months in patients with dependable adherence. Baseline genotypic testing for resistance should be performed in all treatment-naive patients and in cases of confirmed virologic failure (A1a). HLA-B*5701 haplotype screening should be performed in patients for whom abacavir is considered. Assessment of viral tropism is recommended before using maraviroc.

Therapeutic drug monitoring is not recommended in routine care; selected patients might benefit from this intervention.\textsuperscript{2}

\(^1\text{HIV-1 RNA level should be monitored at about 4 weeks after treatment is initiated or changed, and then every 3 months to confirm suppression of viremia below the limit of quantification of sensitive commercial assays (A1a). CD4 cell count should be monitored at least every 3 months after initiation of therapy, especially among patients with cell counts of \(<200/µL\), to determine the need for initiation or discontinuation of primary opportunistic infection prophylaxis (Bill). Once HIV-1 RNA level is suppressed for 1 year and CD4 cell count is stable at \(\geq 350/µL\), viral load and CD4 cell count can be monitored at intervals of \(\leq 6\) months in patients with dependable adherence (CIII).}

\(^2\# Detection limits (\(<20-75\) copies/mL) should occur by 24 weeks regardless of prior treatment experience.

Maintenance of regimen potency is the objective when switching ART regimens. Virologic failure of an initial regimen (confirmed measurable viremia) should be identified and treated as early as possible with at least 2 fully active drugs to avoid the accumulation of resistance mutations. For NNRTI failures, the new combination usually should include a PI/r or an agent from a new class if a PI/r is not possible. Etravirine may be a useful component of a new regimen for NNRTI failure but must be supported by a potent combination including a PI/r. Depending on the resistance profile and options available, inclusion of agents from new drug classes (raltegravir or maraviroc) should be considered. Monotherapy with a PI/r should be avoided unless other drugs cannot be considered for reasons of toxicity/tolerability. Design of a new regimen should consider previous drug exposure, previous resistance profile, drug interactions, and history of intolerance/toxicity. Treatment interruptions should be avoided, except in the context of controlled clinical trials. Elective treatment interruptions should consider the different half-lives of the regimen components, with stopping the drugs in a staggered manner when an NNRTI is a component.\textsuperscript{12}
Evidence Based Practice


c

The Agency for Healthcare Research and Quality (AHRQ) has published the following report(s):
  - **Strategies for Improving the Lives of Women Aged 40+ Living With HIV/AIDS**\(^\text{13}\) (click here)

Approximately 24% of the population living with HIV/AIDS is women with an increase of cases among women over 40. The AHRQ notes considerations for women who not only live with HIV/AIDS but also with the medical and social conditions that accompany aging. The AHRQ identifies and characterizes empirical studies of strategies for the comprehensive management of women over 40, including transgender women, who live with HIV/AIDS. The report also includes strategies to improve the comprehensive care of older women with HIV/AIDS as well as outlines resources from a sample of six states (Rhode Island, Mississippi, Alabama, New York, California, Texas), and illustrates the importance of integrated care. The need to prioritize additional research in this population is also noted.

MEASUREMENT OF COMPLIANCE

WellCare is committed to adhering to the measures and standards published by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please reference WellCare’s Clinical Policy Guiding Document titled Quality Improvement.

NOTE: To access Clinical Policy Guiding Documents visit [www.wellcare.com](http://www.wellcare.com) – select the Provider tab, then “Tools” and “Clinical Guidelines”.

Care Management

The goals for Care Management is to support the member's ability to self-promote their health, encourage healthy behaviors to minimize risks of disease and/or complications thereof, and remove barriers preventing the member from achieving those goals. Primary symptoms for assessment and member education include:

- Educate member on risk factors for HIV and importance of Screening.
- Assist with establishing with Provider experienced in treating patients with HIV.
- Assist with appointments/transportation for follow-up HIV medical care visits
- Assess for and coordinate referral to Behavioral Health for Substance Use, Depression, and other Behavioral Health conditions.
- Assist with coordinating Pregnancy related services to reduce the risk of sexual or perinatal transmission during recognized pregnancy
- Assess for and coordinate community resources to address transportation and other socio-economic barriers to adherence to treatment plan
- Educate member on management of side effects of ART
- Educate member on signs and symptoms to seek medical care

Early Stage of HIV Flu-like symptoms may include:

- Fever
- Chills
- Rash
- Night sweats
- Muscle aches
- Sore throat
- Fatigue
- Swollen lymph nodes
- Mouth ulcers

Progression to AIDS Symptoms can include:

- Rapid weight loss
- Recurring fever or profuse night sweats
- Extreme and unexplained tiredness
- Prolonged swelling of the lymph glands in the armpits, groin, or neck
- Diarrhea that lasts for more than a week
- Sores of the mouth, anus, or genitals
- Pneumonia
- Red, brown, pink, or purplish blotches on or under the skin or inside the mouth, nose, or eyelids
- Memory loss, depression, and other neurologic disorders
MEASURABLE HEALTH OUTCOMES

Targeted Health Outcomes (Extended Program Goals) result from successful member self-management (see Case Management Objectives).

1. The member reports fewer or lessening symptoms over a specific period of time after the start of Case Management engagement. Member-specific goals should reference member’s individual symptoms. Compare member’s symptom assessment responses, initial to subsequent assessments.

2. The member experiences no symptoms requiring acute medical care and intervention. Compare pre- and post-engagement utilization frequency for HIV/AIDS related conditions. Monitor for ED and inpatient authorization/utilization related to the primary diagnosis of HIV. In absence of ED and inpatient utilization, authorizations and claims data, or to otherwise demonstrate less frequent need for acute medical intervention, CM may use Provider and/or Member narrative.

CASE MANAGEMENT GOALS

Case Goals should target specific care gaps and/or adherence issues, and measure the member’s progress towards self-management and adherence which will lead to the targeted health outcomes above. Examples:

1. The Member attends initial and follow up appointments with HIV Provider per treatment team recommendations over last 90 days. (verified by claims or member/provider narrative)

2. The Member’s prescription refills demonstrate at least an 80% adherence rate (verified by claims or member/provider narrative) over last 30 days.

3. The Member is adherent to labs and diagnostics prescribed by the physician (verified by claims or member/provider narrative) over last 30 days.

4. Specific for Members requiring hospitalization: The Member participates in provider follow-up visit within 7 days of hospital discharge.

Other measureable health outcomes may apply based on complications and comorbidities in the individual. Refer to those other CPGs for additional options for health outcomes.

CASE MANAGEMENT OBJECTIVES

Case Management Objectives should focus on improving the member’s self-management skills including:

- Following physician-recommended treatment plan
- Managing side effects of ART per treatment team recommendations
- Taking ART medications as prescribed. Always check with the physician before taking any drugs not prescribed by the physician
- Adhering to provider visit(s) as scheduled
- Early identification of oncoming symptoms (listed above) to report timely to physician
- The care team should also conduct risk screening and treat anxiety and depression, if applicable.
- Educate member on risk factors for HIV and importance of Screening.

In addition, the following should be addressed:

- Prevention
- HIV Screening
- Screen for and treat depression
- Screen for and address socio-economic barriers to adherence to treatment plan
- Assist with establishing with specialist
- Follow up appointments

DIAGNOSTIC TESTING AND COUNSELING

HIV infection usually is diagnosed by tests for antibodies against HIV-1. Some combination tests also detect antibodies against HIV-2 (i.e., HIV-1/2). Antibody testing begins with a sensitive screening test (e.g., the enzyme immunoassay [EIA] or rapid test). The advent of HIV rapid testing has enabled clinicians to make a substantially accurate presumptive diagnosis of HIV-1 infection within half an hour. This testing can facilitate the identification of the more than 250,000 persons living with undiagnosed HIV in the United States. Reactive screening tests must be confirmed by supplemental test (e.g., the Western blot [WB]) or an immunofluorescence assay (IFA). The following are specific recommendations...
for diagnostic testing for HIV infection:

- HIV screening is recommended for all persons who seek evaluation and treatment for STDs;
- HIV testing must be voluntary;
- Consent for HIV testing should be incorporated into the general consent for care (verbally or in writing) with an opportunity to decline (opt-out screening);
- HIV rapid testing can be considered, especially in clinics where patient are unlikely to return for test results;
- Positive screening tests for HIV antibody must be confirmed by a supplemental test (either WB or IFA) before being considered diagnostic of HIV infection;
- Persons who have positive HIV test results (screening and confirmatory) must receive initial HIV prevention counseling before leaving the testing site. Such persons should 1) receive a medical evaluation and, if indicated, behavioral and psychological services, or 2) be referred for these services;
- Providers should be alert to the possibility of acute retroviral syndrome and should perform nucleic acid testing for HIV, if indicated. Patients suspected of having recently acquired HIV infection should be referred for immediate consultation with a specialist.

NOTE: Health-care providers should be knowledgeable about the symptoms and signs of acute retroviral syndrome, which is characterized by fever, malaise, lymphadenopathy, and skin rash. This syndrome frequently occurs in the first few weeks after HIV infection, before antibody test results become positive. Suspicion of acute retroviral syndrome should prompt nucleic acid testing (HIV plasma ribonucleic acid [RNA]) to detect the presence of HIV, although not all nucleic acid tests are approved for diagnostic purposes; a positive HIV nucleic acid test should be confirmed by subsequent antibody testing to document seroconversion (using standard methods, EIA, and WB). Acutely infected patients might be highly contagious because of increased plasma and genital HIV RNA concentrations and might be continuing to engage in risky behaviors. Current guidelines suggest that persons with recently acquired HIV infection might benefit from antiretroviral drugs, and such patients may be candidates for clinical trials. Therefore, patients with acute HIV infection should be referred immediately to an HIV clinical care provider.

Persons can be expected to be distressed when first informed of a positive HIV test result. Such persons face multiple major adaptive challenges, including:

- Accepting the possibility of a shortened life span;
- Coping with the reactions of others to a stigmatizing illness;
- Developing and adopting strategies for maintaining physical and emotional health; and,
- Initiating changes in behavior to prevent HIV transmission to others.

Many persons will require assistance with making reproductive choices, gaining access to health services, confronting possible employment or housing discrimination, and coping with changes in personal relationships. Therefore, behavioral and psychosocial services are an integral part of health care for HIV-infected persons. Such services should be available on site or through referral when HIV infection is diagnosed. The following are specific recommendations for counseling and referral:

- Persons who test positive for HIV antibody should be counseled, either on site or through referral, concerning the behavioral, psychosocial, and medical implications of HIV infection;
- Health-care providers should be alert for medical or psychosocial conditions that require immediate attention;
- Providers should assess newly diagnosed patients' need for immediate medical care or support needs and link them to services in which health-care personnel are experienced in providing care for HIV-infected persons. Such persons might need medical care or services for substance abuse, mental health disorders, emotional distress, reproductive counseling, risk-reduction counseling, and case management. Providers should follow-up to ensure that patients have received the needed services; and,
- Patients should be educated regarding what to expect in follow-up medical care.

**MEDICAL BEHAVIORAL INTEGRATION**

People with HIV have higher rates of behavioral health disorders than the general public and people who abuse drugs or alcohol are at a greater risk of contracting HIV due to risky behaviors such as unsafe sex and needle sharing. The prevalence of HIV among people diagnosed with behavioral health disorders is four times higher than in the general population. Of people diagnosed with HIV 66% of them have used illegal drugs and they have two to five times higher rates of depression. People with HIV are also as much as 20 times more likely to have experienced trauma. For these reasons people with HIV should be screened for behavioral health and substance use disorders. The stress of being diagnosed with HIV can contribute to behavioral health problems as well as the HIV virus itself can contribute to behavioral health problems as it enters and resides in the brain. Opportunistic infections can also affect the nervous system and lead to behavioral and functional changes. Neuropsychological disorders such as cognitive changes or
dementia are also associated with HIV. Depression is one of the most common behavioral health conditions diagnosed with those with HIV. Some antiretroviral medications may cause depressive symptoms, anxiety, and sleep disturbances which can exacerbate behavioral health conditions. People with Behavioral Health conditions and HIV often have instances of a more rapid progression of disease which often comes from increased instances of non-adherence to HIV medication and also a lower immune response due to stress and depression. Use of antidepressants improves adherence to antiretroviral medications. People diagnosed with behavioral health disorders and HIV also have a higher incidence of transmitting the virus to others related to higher instances of poor judgement and impulsivity.

**SPECIAL CONSIDERATIONS**

Management of Sex Partners and Injecting-Drug Partners. The following are specific recommendations for implementing partner-notification procedures:

- HIV-infected patients should be encouraged to notify their partners and to refer them for counseling and testing. If requested by the patient, health-care providers should assist in this process, either directly or by referral to health department partner-notification programs;
- If patients are unwilling to notify their partners or if they cannot ensure that their partners will seek counseling, physicians or health department personnel should use confidential partner notification procedures; and,
- Partners who are contacted within 72 hours of a high-risk sexual or injecting-drug exposure to an HIV-infected partner, which involves exposure to genital secretions and/or blood, should be offered post-exposure prophylaxis (PEP) with combination antiretroviral therapy to complete a 28-day course.

Pregnant Women. Please refer to the section above for information by the American Congress of Obstetricians and Gynecologists.

**MEMBER EDUCATIONAL RESOURCES**

There are currently no Krames educational materials available for this topic.

**PHARMACOLOGY**

Antiretroviral therapy (ART) refers to the use of pharmacologic agents that have specific inhibitory effects on HIV replication. The use of less than three active agents is not recommended for initiating treatment. These agents belong to six distinct classes of drugs: the nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs, NtRTIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs), the protease inhibitors (PIs), the fusion inhibitors (FIs), the CCR5 co-receptor antagonists, and the integrase strand transfer inhibitors (INSTIs).

Clinicians should prescribe an ART regimen that is best able to delay disease progression, prolong survival, and maintain quality of life through maximal viral suppression. The clinician should involve the patient in the decision-making process when determining whether to implement ART. The clinician should review the benefits and risks of treatment for each individual patient. Goals of ART include:

- Maximal and durable suppression of viral replication (measured by viral load assays)
- Restoration and/or preservation of immune function
- Reduced HIV-related morbidity and mortality
- Improved quality of life
- Limitation of the likelihood of viral resistance to preserve future treatment option

Benefits of early ART in asymptomatic HIV-infected patients (initiation at CD4 counts >500 cells/mm3) includes:

- Preservation and/or restoration of immune function and compromise
- Improvement of overall health and the prolongation of life
- Possible lower risk of antiretroviral resistance
- Suppression of viral replication
- Possible decrease in risk of viral transmission to others (including fetal transmission)

Risks of ART include:

- Adverse effects of the medications on quality of life
- Possibility of greater cumulative side effects from ART
- Known, and as yet unknown, long-term drug toxicities, including potential fetal toxicity
Possibility for earlier development of treatment fatigue and viral suppression are suboptimal
Development of HIV drug resistance to drugs currently available and possibly to those not yet available, which may limit future treatment options
Possibility for earlier onset of treatment fatigue
Higher prescription drug costs for the individual

NOTE: The risk of viral transmission still exists even when the plasma viral load is undetectable; ART is not a substitute for other prevention measures (e.g., avoiding sharing needles, practicing safer sex).

Related WellCare Guidelines

In addition to the information contained in this document, please refer to the following age-specific Preventive Health CPGs: Adolescent (HS-1051), Adult (HS-1018), Older Adult (HS-1063), and Pediatric (HS-1019).

NOTE: Clinical Policies can be accessed by going to www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

References


3. Routine behavioral health screening in HIV care and may not be updated with the most current information available at subsequent times. Individuals should consult with their physician(s) regarding the appropriateness of care or treatment options to meet their specific needs or medical condition. Disclosure of a CPG is not a guarantee of coverage and is not intended to be used for Utilization Management Decisions or for claims. Members of WellCare Health Plans should consult their individual coverage documents for information regarding covered benefits. WellCare does not offer medical advice or provide medical care, and therefore cannot guarantee any results or outcomes. WellCare does not warrant or guarantee, and shall not be liable for any deficiencies in the information contained herein or for any inaccuracies or recommendations made by independent third parties from whom any of the information contained herein was obtained. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

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Easy Choice Health Plan – Harmony Health Plan of Illinois – Missouri Care – ‘Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona
OneCare (Care1st Health Plan Arizona, Inc.) – Staywell of Florida – – WellCare Prescription Insurance – WellCare Texan Plus (Medicare – Dallas and Houston markets)
WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

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### Medical Policy Committee Approval History

<table>
<thead>
<tr>
<th>Date</th>
<th>History and Revisions by the Medical Policy Committee</th>
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<tbody>
<tr>
<td>5/3/2018</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>7/24/2017</td>
<td>Approved by MPC. Includes HIV Antiretroviral Treatment: HS-1023 (retired). Included new sections on Care Management and Health Equity, Health Literacy, and Cultural Considerations.</td>
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<td>4/22/2016</td>
<td>Approved by MPC. Additional language added re: USPSTF and ACOG recommendations.</td>
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