HIV Overview

HIV and AIDS: The Basics

Key Points

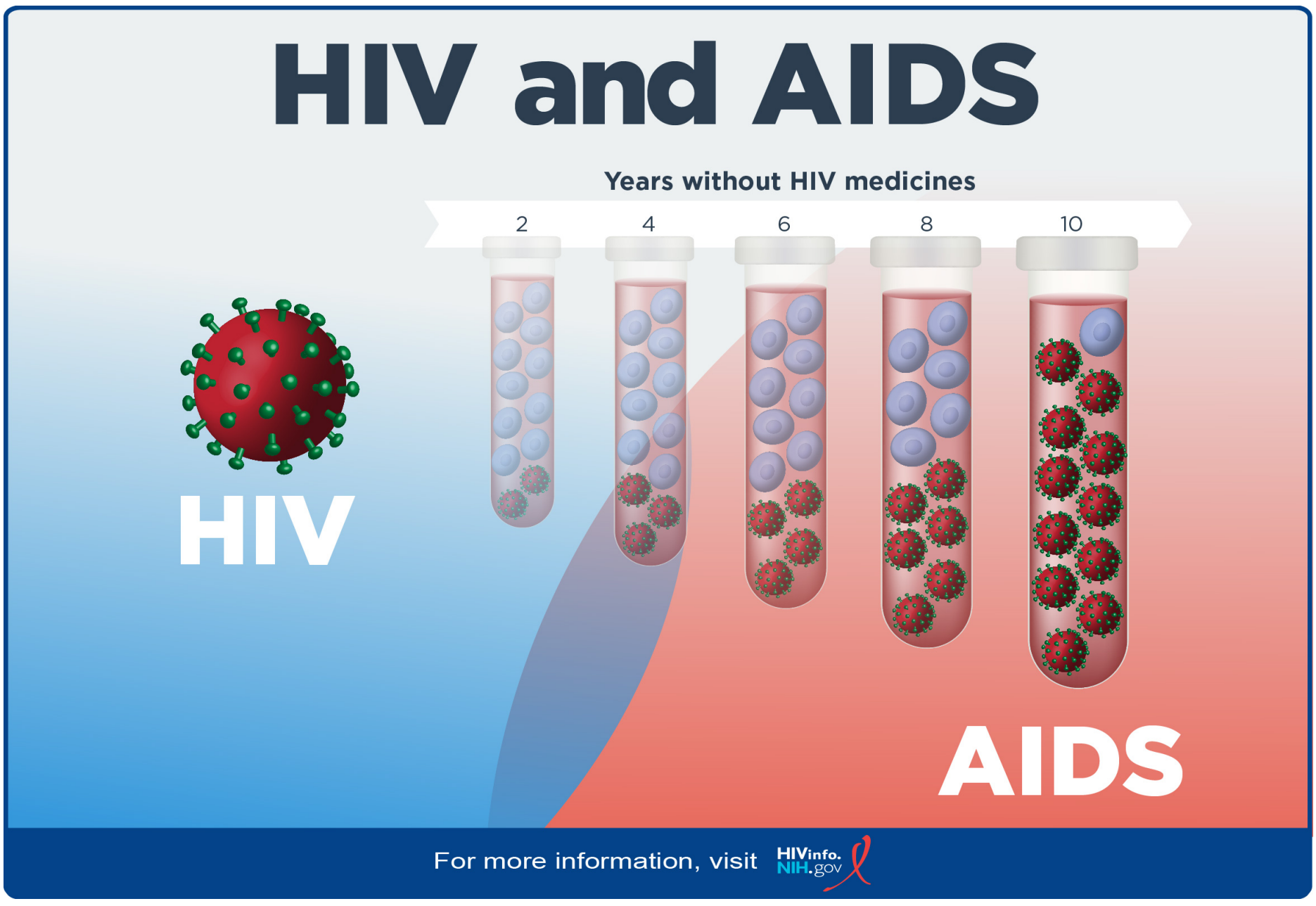
- The human immunodeficiency virus (HIV) is the virus that causes HIV infection. HIV causes acquired immunodeficiency syndrome (AIDS), the most advanced stage of HIV infection.
- HIV is spread through contact with the blood, semen, pre-seminal fluid, rectal fluids, vaginal fluids, or breast milk of a person with HIV. In the United States, HIV is spread mainly by having anal or vaginal sex or sharing injection drug equipment, such as syringes or needles, with a person who has HIV.
- Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. People on ART take a combination of HIV medicines (called an HIV treatment regimen) every day.
- ART is recommended for everyone who has HIV. ART cannot cure HIV infection, but HIV medicines help people with HIV live longer, healthier lives. HIV medicines can also reduce the risk of HIV transmission.

What is HIV and AIDS?

HIV stands for human immunodeficiency virus, which is the virus that causes HIV infection. The abbreviation "HIV" can refer to the virus or to HIV infection.

AIDS stands for acquired immunodeficiency syndrome. AIDS is the most advanced stage of HIV infection.

HIV attacks and destroys the infection-fighting CD4 cells (CD4 T lymphocyte) of the immune system. The loss of CD4 cells makes it difficult for the body to fight off infections and certain cancers. Without treatment, HIV can gradually destroy the immune system and HIV infection advances to AIDS.



How is HIV spread?

The spread of HIV from person to person is called HIV transmission. HIV is spread only through certain body fluids from a

person who has HIV. These body fluids include:

- Blood
- Semen
- Pre-seminal fluid
- Vaginal fluids
- Rectal fluids
- Breast milk

HIV transmission is only possible through contact with HIV-infected body fluids. In the United States, HIV is spread mainly by:

- Having anal or vaginal sex with someone who has HIV without using a condom or taking medicines to prevent or treat HIV
- Sharing injection drug equipment (works), such as needles or syringes, with someone who has HIV

The spread of HIV from a woman with HIV to her child during pregnancy, childbirth, or breastfeeding is called perinatal transmission of HIV. For more information, read the HIVinfo fact sheet on Preventing Perinatal Transmission of HIV.

You cannot get HIV by shaking hands or hugging a person who has HIV. You also cannot get HIV from contact with objects, such as dishes, toilet seats, or doorknobs, used by a person with HIV. HIV is not spread through the air or water or by mosquitoes, ticks, or other blood-sucking insects. Use the HIVinfo You Can Safely Share...With Someone With HIV infographic to spread this message.

How can a person reduce the risk of getting HIV?

To reduce your risk of HIV infection, use condoms correctly every time you have sex, limit your number of sexual partners, and never share injection drug equipment.

Also talk to your health care provider about pre-exposure prophylaxis (PrEP). PrEP is an HIV prevention option for people who do not have HIV but who are at high risk of becoming infected with HIV. PrEP involves taking a specific HIV medicine every day. For more information, read the HIVinfo fact sheet on Pre-exposure Prophylaxis (PrEP).

HIV medicines, given to women with HIV during pregnancy and childbirth and to their babies after birth, reduce the risk of perinatal transmission of HIV. In addition, because HIV can be transmitted through breast milk, women with HIV who live in the United States should not breastfeed their babies. Baby formula is a safe and healthy alternative to breast milk and is readily available in the United States.

What is the treatment for HIV?

Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. People on ART take a combination of HIV medicines (called an HIV treatment regimen) every day.

ART is recommended for everyone who has HIV. ART prevents HIV from multiplying, which reduces the amount of HIV in the body (called the viral load). Having less HIV in the body protects the immune system and prevents HIV infection from advancing to AIDS. ART cannot cure HIV, but HIV medicines help people with HIV live longer, healthier lives.

ART also reduces the risk of HIV transmission. A main goal of ART is to reduce a person's viral load to an undetectable level. An undetectable viral load means that the level of HIV in the blood is too low to be detected by a viral load test. People with HIV who maintain an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative partner through sex.

What are the symptoms of HIV and AIDS?

Within 2 to 4 weeks after infection with HIV, some people may have flu-like symptoms, such as fever, chills, or rash. The symptoms may last for a few days to several weeks. Other possible symptoms of HIV include night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, and mouth ulcers. Having these symptoms do not mean you have HIV. Other illnesses can cause the same symptoms. Some people may not feel sick during early HIV infection (called acute HIV infection). During this earliest stage of HIV infection, the virus multiplies rapidly. After the initial stage of infection, HIV continues to multiply but at very low levels.

More severe symptoms of HIV infection, such as a badly damaged immune system and signs of opportunistic infections, generally do not appear for many years until HIV has advanced to AIDS. People with AIDS have badly damaged immune systems that make them prone to opportunistic infections. (Opportunistic infections are infections and infection-related cancers that occur more frequently or are more severe in people with weakened immune systems than in people with healthy immune systems.)

Without treatment with HIV medicines, HIV infection usually advances to AIDS in 10 years or longer, though it may advance faster in some people.

HIV transmission is possible at any stage of HIV infection—even if a person with HIV has no symptoms of HIV.

How is AIDS diagnosed?

Symptoms such as fever, weakness, and weight loss may be a sign that a person's HIV has advanced to AIDS. However, a diagnosis of AIDS is based on the following criteria:

- A drop in CD4 count to less than 200 cells/mm^3. A CD4 count measures the number of CD4 cells in a sample of blood.

  OR

- The presence of certain opportunistic infections.

Although an AIDS diagnosis indicates severe damage to the immune system, HIV medicines can still help people at this stage of HIV infection.

This fact sheet is based on information from the following sources:

From Centers for Disease Control and Prevention:

- HIV Basics
- About HIV
- AIDS and Opportunistic Infections

From the Department of Health and Human Services (HHS):

- Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection:
  - Introduction

From the National Institute of Allergy and Infectious Diseases (NIAID):

- HIV/AIDS

Also see the HIV Source collection of HIV links and resources.

The HIV Life Cycle

Key Points

- HIV attacks and destroys the CD4 cells (CD4 T lymphocyte) of the immune system. CD4 cells play a major role in protecting the body from infection.
- HIV uses the machinery of the CD4 cells to multiply and spread throughout the body. This process, which is carried out in seven steps or stages, is called the HIV life cycle. HIV medicines protect the immune system by blocking HIV at different stages of the HIV life cycle.
- Antiretroviral therapy (ART) is the use of a combination of HIV medicines to treat HIV infection. People on ART take a combination of HIV medicines from at least two different HIV drug classes every day. Because each class of drugs is designed to target a specific step in the HIV life cycle, ART is very effective at preventing HIV from multiplying.

What is the HIV life cycle?

HIV attacks and destroys the CD4 cells (CD4 T lymphocyte) of the immune system. CD4 cells are a type of white blood cell that play a major role in protecting the body from infection. HIV uses the machinery of the CD4 cells to multiply and spread throughout the body. This process, which is carried out in seven steps or stages, is called the HIV life cycle.

What is the connection between the HIV life cycle and HIV medicines?

Antiretroviral therapy (ART) is the use of a combination of HIV medicines to treat HIV infection. People on ART take a combination of HIV medicines (called an HIV treatment regimen) every day. HIV medicines protect the immune system by blocking HIV at different stages of the HIV life cycle. HIV medicines are grouped into different drug classes according to how they fight HIV. Each class of drugs is designed to target a specific step in the HIV life cycle.

Because an HIV treatment regimen includes HIV medicines from at least two different HIV drug classes, ART is very effective at preventing HIV from multiplying. Having less HIV in the body protects the immune system and prevents HIV from advancing to acquired immunodeficiency syndrome (AIDS).

ART cannot cure HIV, but HIV medicines help people with HIV live longer, healthier lives. HIV medicines also reduce the risk of HIV transmission (the spread of HIV to others).

What are the seven stages of the HIV life cycle?

The seven stages of the HIV life cycle are: 1) binding, 2) fusion, 3) reverse transcription, 4) integration, 5) replication, 6) assembly, and 7) budding.

To understand each stage in the HIV life cycle, it helps to first imagine what HIV looks like.

Now, follow each stage in the HIV life cycle as HIV attacks a CD4 cell and uses the machinery of the cell to multiply.

This fact sheet is based on information from the following sources:

From the National Institute of Allergy and Infectious Diseases:

- HIV Replication Cycle
- Antiretroviral Drug Discovery and Development

Also see the HIV Source collection of HIV links and resources.

The Stages of HIV Infection

Key Points

- Without treatment with HIV medicines, HIV infection advances in stages, getting worse over time.
- The three stages of HIV infection are (1) acute HIV infection, (2) chronic HIV infection, and (3) acquired immunodeficiency syndrome (AIDS).
- There is no cure for HIV, but treatment with HIV medicines (called antiretroviral therapy or ART) can slow or prevent HIV from advancing from one stage to the next. HIV medicines help people with HIV live longer, healthier lives.

HIV Infection

Without treatment, HIV infection advances in stages, getting worse over time. HIV gradually destroys the immune system and eventually causes acquired immunodeficiency syndrome (AIDS).

There is no cure for HIV, but treatment with HIV medicines (called antiretroviral therapy or ART) can slow or prevent HIV from

advancing from one stage to the next. HIV medicines help people with HIV live longer, healthier lives. One of the main goals of ART is to reduce a person's viral load to an undetectable level. An undetectable viral load means that the level of HIV in the blood is too low to be detected by a viral load test. People with HIV who maintain an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative partner through sex.

HIV Progression

There are three stages of HIV infection:

1. ### Acute HIV Infection

   Acute HIV infection is the earliest stage of HIV infection, and it generally develops within 2 to 4 weeks after infection with HIV. During this time, some people have flu-like symptoms, such as fever, headache, and rash. In the acute stage of infection, HIV multiplies rapidly and spreads throughout the body. The virus attacks and destroys the infection-fighting CD4 cells (CD4 T lymphocyte) of the immune system. During the acute HIV infection stage, the level of HIV in the blood is very high, which greatly increases the risk of HIV transmission. A person may experience significant health benefits if they start ART during this stage.

2. ### Chronic HIV Infection

   The second stage of HIV infection is chronic HIV infection (also called asymptomatic HIV infection or clinical latency). During this stage, HIV continues to multiply in the body but at very low levels. People with chronic HIV infection may not have any HIV-related symptoms. Without ART, chronic HIV infection usually advances to AIDS in 10 years or longer, though in some people it may advance faster. People who are taking ART may be in this stage for several decades. While it is still possible to transmit HIV to others during this stage, people who take ART exactly as prescribed and maintain an undetectable viral load have effectively no risk of transmitting HIV to an HIV-negative partner through sex.

3. ### AIDS

   AIDS is the final, most severe stage of HIV infection. Because HIV has severely damaged the immune system, the body cannot fight off opportunistic infections. (Opportunistic infections are infections and infection-related cancers that occur more frequently or are more severe in people with weakened immune systems than in people with healthy immune systems.) People with HIV are diagnosed with AIDS if they have a CD4 count of less than 200 cells/mm3 or if they have certain opportunistic infections. Once a person is diagnosed with AIDS, they can have a high viral load and are able to transmit HIV to others very easily. Without treatment, people with AIDS typically survive about 3 years.

This fact sheet is based on information from the following sources:

From HIV.gov:

- What Are HIV and AIDS?

From the Centers for Disease Control and Prevention (CDC):

- About HIV

Also see the HIV Source collection of HIV links and resources.

What is a Latent HIV Reservoir?

Key Points

- A latent HIV reservoir is a group of immune system cells in the body that are infected with HIV but are not actively producing new HIV.
- Finding ways to target and destroy latent reservoirs is a major challenge facing HIV researchers who are exploring different strategies for clearing out reservoirs.

What is a latent HIV reservoir?

A latent HIV reservoir is a group of immune system cells in the body that are infected with HIV but are not actively producing

new virus.

HIV attacks immune system cells in the body and uses the cells' own machinery to make copies of itself. However, some HIV-infected immune cells go into a resting or latent state. While in this resting state, the infected cells do not produce new virus. HIV can hide inside these cells for years, forming a latent HIV reservoir but, at any time, cells in the latent reservoir can become active again and start making more virus.

To find out more about how HIV attacks cells, read the HIV Life Cycle fact sheet from HIVinfo.

Do HIV medicines work against latent HIV reservoirs?

HIV medicines prevent HIV from multiplying, which reduces the amount of the virus in the body (called the viral load). Because the HIV-infected cells in a latent reservoir are not producing new copies of the virus, HIV medicines have no effect on them.

People with HIV must take a daily combination of HIV medicines (called an HIV treatment regimen) to keep their viral loads low. If a person stops taking their HIV medicines, the infected cells of the latent reservoir can begin making HIV again and the person's viral load will increase. That is why it is important to continue taking HIV medicines every day as prescribed, even when viral load levels are low.

Are researchers studying ways to target latent HIV reservoirs?

Finding ways to target and destroy latent reservoirs is a major challenge facing HIV researchers. Researchers are exploring different strategies for clearing out reservoirs, including:

- Using gene therapy (manipulating genes to treat or prevent disease) to cut out certain HIV genes and inactivate the virus in HIV-infected immune cells.
- Developing drugs or other methods to reactivate latent HIV so that the HIV can be destroyed by the immune system or new HIV therapies. This means of eliminating latent HIV reservoirs is sometimes known as the "shock and kill" or "kick and kill" strategy.

This fact sheet is based on information from the following sources:

From the National Institute of Allergy and Infectious Diseases:

- HIV/AIDS Treatment
- HIV Viral Eradication
- Sustained ART-Free HIV Remission

Also see the HIV Source collection of HIV links and resources.

HIV Testing

Key Points

- HIV testing determines if a person is infected with HIV. The human immunodeficiency virus (HIV) is the virus that causes acquired immunodeficiency syndrome (AIDS). AIDS is the most advanced stage of HIV infection.
- The Centers for Disease Control and Prevention (CDC) recommends that everyone 13 to 64 years of age get tested for HIV at least once as part of routine health care and that people at higher risk for HIV get tested more often. If you are over 64 years of age and at risk for HIV, your health care provider may recommend HIV testing.
- Risk factors for HIV include having vaginal or anal sex with someone who is HIV positive or whose HIV status you do not know; having sex with many partners; and injecting drugs and sharing needles, syringes, or other drug equipment with others.
- CDC recommends that all pregnant women get tested for HIV so that they can begin taking HIV medicines if they are HIV positive.

What is HIV testing?

HIV testing determines if a person is infected with HIV. The human immunodeficiency virus (HIV) is the virus that causes acquired immunodeficiency syndrome (AIDS). AIDS is the most advanced stage of HIV infection.

HIV testing can detect HIV infection, but it cannot tell how long a person has had HIV or if the person has AIDS.

Why is HIV testing important?

Knowing your HIV status can help keep you—and others—safe.

If you are HIV negative:

A negative HIV test result shows that you do not have HIV. Continue taking steps to avoid getting HIV, such as using condoms during sex and, if you are at high risk of getting HIV, taking medicines to prevent HIV (called pre-exposure prophylaxis or PrEP). For more information, read the HIVinfo fact sheet on The Basics of HIV Prevention.

If you are HIV positive:

A positive HIV test result shows that you have HIV, but you can still take steps to protect your health. Begin by talking to your health care provider about antiretroviral therapy (ART). People on ART take a combination of HIV medicines every day to treat HIV infection. ART is recommended for everyone who has HIV, and people with HIV should start ART as soon as possible. ART cannot cure HIV, but HIV medicines help people with HIV live longer, healthier lives.

A main goal of ART is to reduce a person's viral load to an undetectable level. An undetectable viral load means that the level of HIV in the blood is too low to be detected by a viral load test. People with HIV who maintain an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative partner through sex.

Who should get tested for HIV?

The Centers for Disease Control and Prevention (CDC) recommends that everyone 13 to 64 years of age get tested for HIV at least once as part of routine health care. As a general rule, people at higher risk for HIV should get tested each year. Sexually active gay and bisexual men may benefit from getting tested more often, such as every 3 to 6 months. If you are over 64 years of age and at risk, your health care provider may recommend HIV testing.

Factors that increase the risk of HIV include:

- Having vaginal or anal sex with someone who is HIV positive or whose HIV status you do not know
- Injecting drugs and sharing needles, syringes, or other drug equipment with others
- Exchanging sex for money or drugs
- Having a sexually transmitted disease (STD), such as syphilis
- Having sex with anyone who has any of the HIV risk factors listed above

Talk to your health care provider about your risk for HIV and how often you should get tested for HIV.

Should pregnant women get tested for HIV?

CDC recommends that all pregnant women get tested for HIV so that they can begin taking HIV medicines if they are HIV positive. Women with HIV take HIV medicines during pregnancy and childbirth to reduce the risk of perinatal transmission of HIV and to protect their own health. For more information, read the HIVinfo fact sheet on Preventing Perinatal Transmission of HIV.

What are the types of HIV tests?

There are three types of tests used to diagnose HIV infection: antibody tests, antigen/antibody tests, and nucleic acid tests (NATs). Your health care provider can determine the appropriate HIV test for you. How soon each test can detect HIV infection differs, because each test has a different window period. The window period is the time between when a person may have been exposed to HIV and when a test can accurately detect HIV infection.

- **Antibody tests** check for HIV antibodies in blood or oral fluid. HIV antibodies are disease-fighting proteins that the body produces in response to HIV infection. Most rapid tests and home use tests are antibody tests.
- **Antigen/antibody tests** can detect both HIV antibodies and HIV antigens (a part of the virus) in the blood.
- **NATs** look for HIV in the blood.

A person's initial HIV test will usually be either an antibody test or an antigen/antibody test. NATs are very expensive and not routinely used for HIV screening unless the person had a high-risk exposure or a possible exposure with early symptoms of HIV infection.

When an HIV test is positive, a follow-up test will be conducted. Sometimes people will need to visit a health care provider to take a follow-up test. Other times, the follow-up test may be performed in a lab using the same blood sample that was provided for the first test. A positive follow-up test confirms that a person has HIV.

Talk to your health care provider about your HIV risk factors and the best type of HIV test for you.

Is HIV testing confidential?

HIV testing can be confidential or anonymous.

Confidential testing means that your HIV test results will include your name and other identifying information, and the results will be included in your medical record. HIV-positive test results will be reported to local or state health departments to be counted in statistical reports. Health departments remove all personal information (including names and addresses) from HIV test results before sharing the information with CDC. CDC uses this information for reporting purposes and does not share this information with any other organizations, including insurance companies.

Anonymous testing means you do not have to give your name when you take an HIV test. When you take the test, you receive a number. To get your HIV test results, you give the number instead of your name.

Where can someone get tested for HIV?

Your health care provider can give you an HIV test. HIV testing is also available at many hospitals, medical clinics, substance use programs, and community health centers. Use CDC's GetTested treatment locator to find an HIV testing location near you. Getting tested through a professional health care provider is recommended; however, there are HIV self-testing kits available. Rapid self-test and mail-in self-test are the two types of HIV self-tests, but state laws regarding self-testing may limit their availability in a location.

A rapid self-test is an oral fluid test done entirely at home or in private. There is currently one U.S. Food and Drug Administration (FDA)-approved rapid self-test called OraQuick In-Home HIV test. A mail-in self-test requires a person to provide a blood sample from a fingerstick, which is then sent to a lab for testing.

This fact sheet is based on information from the following sources:

From CDC:

- Getting Tested
- HIV Basics: Testing
- HIV Testing
- Self-Testing
- Self-Testing: A Convenient and Private Option

From FDA:

- OraQuick In-Home HIV Test

Also see the HIV Source collection of HIV links and resources.

FDA-Approved HIV Medicines

Treatment with HIV medicines is called antiretroviral therapy (ART). ART is recommended for everyone with HIV, and people with HIV should start ART as soon as possible. People on ART take a combination of HIV medicines (called an HIV treatment regimen) every day. A person's initial HIV treatment regimen generally includes three HIV medicines from at least two different HIV drug classes.

The following table lists HIV medicines recommended for the treatment of HIV infection in the United States, based on the U.S. Department of Health and Human Services (HHS) HIV/AIDS medical practice guidelines. All of these drugs are approved by the U.S. Food and Drug Administration (FDA). The HIV medicines are listed according to drug class

are approved by the U.S. Food and Drug Administration (FDA). The HIV medicines are listed according to drug class and identified by generic and brand names. Click on a drug name to view information on the drug from the Clinicalinfo Drug Database.

To see a timeline of all FDA approval dates for HIV medicines, view the HIVinfo FDA Approval of HIV Medicines infographic.

FDA-Approved HIV Medicines

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)			
NRTIs block reverse transcriptase, an enzyme HIV needs to make copies of itself.	abacavir (abacavir sulfate, ABC)	Ziagen	December 17, 1998
	emtricitabine (FTC)	Emtriva	July 2, 2003
	lamivudine (3TC)	Epivir	November 17, 1995
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	Retrovir	March 19, 1987
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)			
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	doravirine (DOR)	Pifeltro	August 30, 2018
	efavirenz (EFV)	Sustiva	September 17, 1998
	etravirine (ETR)	Intelence	January 18, 2008
	nevirapine (extended-release nevirapine, NVP)	Viramune	June 21, 1996
		Viramune XR (extended release)	March 25, 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	Edurant	May 20, 2011
Protease Inhibitors (PIs)			
PIs block HIV protease, an enzyme HIV needs to make copies of itself.	atazanavir (atazanavir sulfate, ATV)	Reyataz	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	Prezista	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FOS-APV, FPV)	Lexiva	October 20, 2003
	ritonavir (RTV) *Although ritonavir is a PI, it is generally used as a pharmacokinetic enhancer as recommended in the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV and the Guidelines for the Use of Antiretroviral Agents in Pediatric	Norvir	March 1, 1996

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
	tipranavir (TPV)	Aptivus	June 22, 2005
Fusion Inhibitors			
Fusion inhibitors block HIV from entering the CD4 T lymphocyte (CD4 cells) of the immune system.	enfuvirtide (T-20)	Fuzeon	March 13, 2003
CCR5 Antagonists			
CCR5 antagonists block CCR5 coreceptors on the surface of certain immune cells that HIV needs to enter the cells.	maraviroc (MVC)	Selzentry	August 6, 2007
Integrase Strand Transfer Inhibitor (INSTIs)			
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.	cabotegravir (cabotegravir sodium, CAB)	Vocabria	January 22, 2021
	dolutegravir (dolutegravir sodium, DTG)	Tivicay	August 12, 2013
		Tivicay PD	June 12, 2020
	raltegravir (raltegravir potassium, RAL)	Isentress	October 12, 2007
		Isentress HD	May 26, 2017
Attachment Inhibitors			
Attachment inhibitors bind to the gp120 protein on the outer surface of HIV, preventing HIV from entering CD4 cells.	fostemsavir (fostemsavir tromethamine, FTR)	Rukobia	July 2, 2020
Post-Attachment Inhibitors			
Post-attachment inhibitors block CD4 receptors on the surface of certain immune cells that HIV needs to enter the cells.	ibalizumab-uiyk (Hu5A8, IBA, Ibalizumab, TMB-355, TNX-355)	Trogarzo	March 6, 2018
Pharmacokinetic Enhancers			
Pharmacokinetic enhancers are used in HIV treatment to increase the effectiveness of an HIV medicine included in an HIV treatment regimen.	cobicistat (COBI, c)	Tybost	September 24, 2014
Combination HIV Medicines			
Combination HIV medicines contain two or more HIV medicines from one or more drug classes.	abacavir and lamivudine (abacavir sulfate / lamivudine, ABC / 3TC)	Epzicom	August 2, 2004
	abacavir, dolutegravir, and lamivudine (abacavir sulfate / dolutegravir sodium / lamivudine, ABC / DTG / 3TC)	Triumeq	August 22, 2014
		Triumeq PD	March 30, 2022
	abacavir, lamivudine, and zidovudine (abacavir sulfate / lamivudine / zidovudine, ABC / 3TC / ZDV)	Trizivir	November 14, 2000
	atazanavir and cobicistat (atazanavir sulfate / cobicistat, ATV / COBI)	Evotaz	January 29, 2015
	bictegravir, emtricitabine, and tenofovir alafenamide (bictegravir sodium / emtricitabine /	Biktarvy	February 7, 2018

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
	tenofovir alafenamide fumarate, BIC / FTC / TAF)		
	cabotegravir and rilpivirine (CAB and RPV, CAB plus RPV, Cabenuva kit, cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension)	Cabenuva	January 22, 2021
	darunavir and cobicistat (darunavir ethanolate / cobicistat, DRV / COBI)	Prezcobix	January 29, 2015
	darunavir, cobicistat, emtricitabine, and tenofovir alafenamide (darunavir ethanolate / cobicistat / emtricitabine / tenofovir AF, darunavir ethanolate / cobicistat / emtricitabine / tenofovir alafenamide, darunavir / cobicistat / emtricitabine / tenofovir AF, darunavir / cobicistat / emtricitabine / tenofovir alafenamide fumarate, DRV / COBI / FTC / TAF)	Symtuza	July 17, 2018
	dolutegravir and lamivudine (dolutegravir sodium / lamivudine, DTG / 3TC)	Dovato	April 8, 2019
	dolutegravir and rilpivirine (dolutegravir sodium / rilpivirine hydrochloride, DTG / RPV)	Juluca	November 21, 2017
	doravirine, lamivudine, and tenofovir disoproxil fumarate (doravirine / lamivudine / TDF, doravirine / lamivudine / tenofovir DF, DOR / 3TC / TDF)	Delstrigo	August 30, 2018
	efavirenz, emtricitabine, and tenofovir disoproxil fumarate (efavirenz / emtricitabine / tenofovir DF, EFV / FTC / TDF)	Atripla	July 12, 2006
	efavirenz, lamivudine, and tenofovir disoproxil fumarate (EFV / 3TC / TDF)	Symfi	March 22, 2018
	efavirenz, lamivudine, and tenofovir disoproxil fumarate (EFV / 3TC / TDF)	Symfi Lo	February 5, 2018
	elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide fumarate, EVG / COBI / FTC / TAF)	Genvoya	November 5, 2015
	elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (QUAD, EVG / COBI / FTC / TDF)	Stribild	August 27, 2012
	emtricitabine, rilpivirine, and tenofovir alafenamide (emtricitabine / rilpivirine / tenofovir AF, emtricitabine / rilpivirine / tenofovir alafenamide fumarate, emtricitabine / rilpivirine hydrochloride / tenofovir AF,	Odefsey	March 1, 2016

Drug Class	Generic Name (Other Names)	Brand Name	FDA Approval Date
	alafenamide, emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide fumarate, FTC / RPV / TAF)		
	emtricitabine, rilpivirine, and tenofovir disoproxil fumarate (emtricitabine / rilpivirine hydrochloride / tenofovir disoproxil fumarate, emtricitabine / rilpivirine / tenofovir, FTC / RPV / TDF)	Complera	August 10, 2011
	emtricitabine and tenofovir alafenamide (emtricitabine / tenofovir AF, emtricitabine / tenofovir alafenamide fumarate, FTC / TAF)	Descovy	April 4, 2016
	emtricitabine and tenofovir disoproxil fumarate (emtricitabine / tenofovir DF, FTC / TDF)	Truvada	August 2, 2004
	lamivudine and tenofovir disoproxil fumarate (3TC / TDF)	Cimduo	February 28, 2018
	lamivudine and zidovudine (3TC / ZDV)	Combivir	September 27, 1997
	lopinavir and ritonavir (ritonavir-boosted lopinavir, LPV/r, LPV / RTV)	Kaletra	September 15, 2000

This fact sheet is based on information from the following sources:

From FDA:

- HIV and AIDS: Medicines to Help You

From the National Library of Medicine:

- Drug information from the DailyMed website

Also see the HIV Source collection of HIV links and resources.

FDA-Approved HIV Medicines

Treatment with HIV medicines is called antiretroviral therapy (ART). ART is recommended for everyone with HIV, and people with HIV should start ART as soon as possible. People on ART take a combination of HIV medicines (called an HIV treatment regimen) every day. A person's initial HIV treatment regimen generally includes three HIV medicines from at least two different HIV drug classes.

The following table lists HIV medicines recommended for the treatment of HIV infection in the United States, based on the U.S. Department of Health and Human Services (HHS) HIV/AIDS medical practice guidelines. All of these drugs are approved by the U.S. Food and Drug Administration (FDA). The HIV medicines are listed according to drug class and identified by generic and brand names. Click on a drug name to view information on the drug from the Clinicalinfo Drug Database.

To see a timeline of all FDA approval dates for HIV medicines, view the HIVinfo FDA Approval of HIV Medicines infographic.

FDA-Approved HIV Medicines

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)			
NRTIs block reverse transcriptase, an enzyme HIV needs to make copies of itself.	abacavir (abacavir sulfate, ABC)	Ziagen	December 17, 1998
	emtricitabine (FTC)	Emtriva	July 2, 2003
	lamivudine (3TC)	Epivir	November 17, 1995
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	Retrovir	March 19, 1987
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)			
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	doravirine (DOR)	Pifeltro	August 30, 2018
	efavirenz (EFV)	Sustiva	September 17, 1998
	etravirine (ETR)	Intelence	January 18, 2008
	nevirapine (extended-release nevirapine, NVP)	Viramune	June 21, 1996
		Viramune XR (extended release)	March 25, 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	Edurant	May 20, 2011
Protease Inhibitors (PIs)			
PIs block HIV protease, an enzyme HIV needs to make copies of itself.	atazanavir (atazanavir sulfate, ATV)	Reyataz	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	Prezista	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FOS-APV, FPV)	Lexiva	October 20, 2003
	ritonavir (RTV) *Although ritonavir is a PI, it is generally used as a pharmacokinetic enhancer as recommended in the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.	Norvir	March 1, 1996
	tipranavir (TPV)	Aptivus	June 22, 2005
Fusion Inhibitors			

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approved Date
Fusion inhibitors block HIV from entering the CD4 T lymphocyte (CD4 cells) of the immune system.	enfuvirtide (T-20)	Fuzeon	March 13, 2003
CCR5 Antagonists			
CCR5 antagonists block CCR5 coreceptors on the surface of certain immune cells that HIV needs to enter the cells.	maraviroc (MVC)	Selzentry	August 6, 2007
Integrase Strand Transfer Inhibitor (INSTIs)			
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.	cabotegravir (cabotegravir sodium, CAB)	Vocabria	January 22, 2021
	dolutegravir (dolutegravir sodium, DTG)	Tivicay	August 12, 2013
		Tivicay PD	June 12, 2020
	raltegravir (raltegravir potassium, RAL)	Isentress	October 12, 2007
		Isentress HD	May 26, 2017
Attachment Inhibitors			
Attachment inhibitors bind to the gp120 protein on the outer surface of HIV, preventing HIV from entering CD4 cells.	fostemsavir (fostemsavir tromethamine, FTR)	Rukobia	July 2, 2020
Post-Attachment Inhibitors			
Post-attachment inhibitors block CD4 receptors on the surface of certain immune cells that HIV needs to enter the cells.	ibalizumab-uiyk (Hu5A8, IBA, Ibalizumab, TMB-355, TNX-355)	Trogarzo	March 6, 2018
Pharmacokinetic Enhancers			
Pharmacokinetic enhancers are used in HIV treatment to increase the effectiveness of an HIV medicine included in an HIV treatment regimen.	cobicistat (COBI, c)	Tybost	September 24, 2014
Combination HIV Medicines			
Combination HIV medicines contain two or more HIV medicines from one or more drug classes.	abacavir and lamivudine (abacavir sulfate / lamivudine, ABC / 3TC)	Epzicom	August 2, 2004
	abacavir, dolutegravir, and lamivudine (abacavir sulfate / dolutegravir sodium / lamivudine, ABC / DTG / 3TC)	Triumeq	August 22, 2014
		Triumeq PD	March 30, 2022
	abacavir, lamivudine, and zidovudine (abacavir sulfate / lamivudine / zidovudine, ABC / 3TC / ZDV)	Trizivir	November 14, 2000
	atazanavir and cobicistat (atazanavir sulfate / cobicistat, ATV / COBI)	Evotaz	January 29, 2015
	bictegravir, emtricitabine, and tenofovir alafenamide (bictegravir sodium / emtricitabine / tenofovir alafenamide fumarate, BIC / FTC / TAF)	Biktarvy	February 7, 2018
	cabotegravir and rilpivirine (CAB and RPV, CAB plus RPV, Cabenuva kit, cabotegravir extended-release injectable suspension and	Cabenuva	January 22, 2021

Drug Class	Generic Name (Select names and acronyms)	Brand Name	FDA Approval Date
	rilpivirine extended-release injectable suspension)		
	darunavir and cobicistat (darunavir ethanolate / cobicistat, DRV / COBI)	Prezcobix	January 29, 2015
	darunavir, cobicistat, emtricitabine, and tenofovir alafenamide (darunavir ethanolate / cobicistat / emtricitabine / tenofovir AF, darunavir ethanolate / cobicistat / emtricitabine / tenofovir alafenamide, darunavir / cobicistat / emtricitabine / tenofovir AF, darunavir / cobicistat / emtricitabine / tenofovir alafenamide fumarate, DRV / COBI / FTC / TAF)	Symtuza	July 17, 2018
	dolutegravir and lamivudine (dolutegravir sodium / lamivudine, DTG / 3TC)	Dovato	April 8, 2019
	dolutegravir and rilpivirine (dolutegravir sodium / rilpivirine hydrochloride, DTG / RPV)	Juluca	November 21, 2017
	doravirine, lamivudine, and tenofovir disoproxil fumarate (doravirine / lamivudine / TDF, doravirine / lamivudine / tenofovir DF, DOR / 3TC / TDF)	Delstrigo	August 30, 2018
	efavirenz, emtricitabine, and tenofovir disoproxil fumarate (efavirenz / emtricitabine / tenofovir DF, EFV / FTC / TDF)	Atripla	July 12, 2006
	efavirenz, lamivudine, and tenofovir disoproxil fumarate (EFV / 3TC / TDF)	Symfi	March 22, 2018
	efavirenz, lamivudine, and tenofovir disoproxil fumarate (EFV / 3TC / TDF)	Symfi Lo	February 5, 2018
	elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide fumarate, EVG / COBI / FTC / TAF)	Genvoya	November 5, 2015
	elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (QUAD, EVG / COBI / FTC / TDF)	Stribild	August 27, 2012
	emtricitabine, rilpivirine, and tenofovir alafenamide (emtricitabine / rilpivirine / tenofovir AF, emtricitabine / rilpivirine / tenofovir alafenamide fumarate, emtricitabine / rilpivirine hydrochloride / tenofovir AF, emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide, emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide fumarate, FTC / RPV / TAF)	Odefsey	March 1, 2016

Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
	emtricitabine, rilpivirine, and tenofovir disoproxil fumarate (emtricitabine / rilpivirine hydrochloride / tenofovir disoproxil fumarate, emtricitabine / rilpivirine / tenofovir, FTC / RPV / TDF)	Complera	August 10, 2011
	emtricitabine and tenofovir alafenamide (emtricitabine / tenofovir AF, emtricitabine / tenofovir alafenamide fumarate, FTC / TAF)	Descovy	April 4, 2016
	emtricitabine and tenofovir disoproxil fumarate (emtricitabine / tenofovir DF, FTC / TDF)	Truvada	August 2, 2004
	lamivudine and tenofovir disoproxil fumarate (3TC / TDF)	Cimduo	February 28, 2018
	lamivudine and zidovudine (3TC / ZDV)	Combivir	September 27, 1997
	lopinavir and ritonavir (ritonavir-boosted lopinavir, LPV/r, LPV / RTV)	Kaletra	September 15, 2000

This fact sheet is based on information from the following sources:

From FDA:

- HIV and AIDS: Medicines to Help You

From the National Library of Medicine:

- Drug information from the DailyMed website

Also see the HIV Source collection of HIV links and resources.

What is an Investigational HIV Drug?

Key Points

- An investigational drug is an experimental drug that is being studied to see whether it is safe and effective.
- Investigational HIV drugs are studied in medical research studies called clinical trials. Once an investigational HIV drug has been proven safe and effective in a clinical trial, the U.S. Food and Drug Administration (FDA) may approve the drug for general use or sale in the United States.
- Investigational HIV drugs being studied include drugs to treat or prevent HIV and vaccines to treat or prevent HIV.
- Investigational HIV drugs can only be accessed through clinical trials and expanded access programs.

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What types of investigational HIV drugs are being studied?

Investigational HIV drugs being studied include drugs to treat HIV and prevent HIV. Some types of investigational HIV drugs being studied include microbicides, immune modulators, latency-reversing agents, gp120 attachment inhibitors, and rev inhibitors.

HIV researchers are also studying investigational vaccines to prevent HIV and treat HIV. The goal of a preventive HIV vaccine is to prevent HIV in people who do not have HIV but who may be exposed to the virus. A safe and effective HIV treatment vaccine (also called a therapeutic HIV vaccine) could prevent HIV from advancing to acquired immunodeficiency syndrome (AIDS), replace the daily use of HIV medicines, and help prevent HIV transmission.

To learn more, read the HIVinfo What is a Preventive HIV Vaccine? and What is a Therapeutic HIV Vaccine? fact sheets.

How are clinical trials of investigational drugs conducted?

Clinical trials are conducted in phases. Each phase has a different purpose and helps researchers answer different questions about the investigational drug.

- **Phase 1 trial**: Initial testing in a small group of people (20–80) to evaluate the drug's safety and to identify side effects.
- **Phase 2 trial**: Testing in a larger group of people (100–300) to determine the drug's effectiveness and to further evaluate its safety.
- **Phase 3 trial**: Continued testing in large groups of people (1,000–3,000) to confirm the drug's effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information to ensure that the investigational drug can be used safely.

  In most cases, an investigational drug must be proven effective and must show continued safety in a Phase 3 clinical trial to be considered for approval by the FDA for sale in the United States. (However, some drugs go through the FDA's accelerated approval process and are approved before a Phase 3 clinical trial is complete.)
- **Phase 4 trial**: Ongoing tracking that occurs after a drug is approved by the FDA for sale in the United States. The purpose of the tracking is to seek more information about the drug's risks, benefits, and optimal use.

For more information, read the HIVinfo HIV and AIDS Clinical Trials fact sheet.

The four phases of a clinical trial.

How can a person find a clinical trial that is studying an investigational HIV drug?

To find an HIV and AIDS clinical trial that is studying an investigational HIV drug, use the find a study search feature on ClinicalTrials.gov.

For help with your search, call a Clinicalinfo health information specialist at 1-800-448-0440 or email ContactUs@HIVinfo.NIH.gov.

You can also join ResearchMatch, which is a free, secure online tool that makes it easier for the public to become involved in clinical trials.

Are investigational HIV drugs available for use outside of a clinical trial?

In some cases, an investigational HIV drug may be available through an expanded access program. Expanded access allows for the use of an investigational drug outside of a clinical trial to treat a person who has a serious or immediate life-threatening disease and who has no FDA-approved treatment options. Drug companies must have permission from the FDA to make an investigational drug available for expanded access.

People seeking expanded access to an investigational HIV drug should talk to their health care provider to see if they may qualify to take part in an expanded access program.

Is it safe to use an investigational HIV drug?

One goal of HIV research is to identify safer, more effective HIV medicines. Researchers try to make clinical trials as safe as possible. However, taking an investigational HIV drug can involve both benefits and risks. Risks may include unexpected side effects from the drug, which can be unpleasant, serious, or even life-threatening.

The benefits and possible risks of participating in a clinical trial or an expanded access program are explained to people before they decide whether to participate.

How can a person find more information on investigational HIV drugs?

To find more information on investigational HIV drugs, use the Clinicalinfo Drug Database, which includes up-to-date information on many investigational HIV drugs.

This fact sheet is based on information from the following sources:

From the National Institutes of Health (NIH):

- NIH Clinical Research Trials and You: The Basics
- NIH Clinical Research Trials and You: Finding a Clinical Trial

From the National Institute of Allergy and Infectious Diseases:

- HIV/AIDS

From the U.S. Food and Drug Administration (FDA):

- Expanded Access | Information for Patients

Also see the HIV Source collection of HIV links and resources.

What is a Therapeutic HIV Vaccine?

Key Points

- A therapeutic HIV vaccine is a vaccine that is designed to improve the body's immune response to HIV in a person who already has HIV.
- Currently, no therapeutic HIV vaccines have been approved by the U.S. Food and Drug Administration (FDA), but research is underway. You must be enrolled in a clinical trial to receive a therapeutic HIV vaccine.
- Researchers are exploring therapeutic HIV vaccines to slow down the progression of HIV infection and to eliminate the need for antiretroviral therapy (ART) while keeping undetectable levels of HIV.

What is a therapeutic HIV vaccine?

A therapeutic HIV vaccine is a vaccine that is designed to improve the body's immune response to HIV in a person who already has HIV.

Researchers are developing and testing therapeutic HIV vaccines to slow down the progression of HIV to acquired immunodeficiency syndrome (AIDS). The hope is that treating people with these vaccines would ideally keep HIV at undetectable levels (known as undetectable viral load) without the need for regular antiretroviral therapy (ART). ART is the recommended treatment for HIV infection and involves using a combination of different HIV medicines to prevent HIV from multiplying. Currently, a person with HIV must remain on ART to keep HIV at undetectable levels.

A therapeutic HIV vaccine may also make it less likely that a person could transmit HIV to others.

Are there any FDA-approved therapeutic HIV vaccines?

There are currently no U.S. Food and Drug Administration (FDA)-approved therapeutic HIV vaccines, but research is underway. You must be enrolled in a clinical trial to receive a therapeutic HIV vaccine.

How is a therapeutic HIV vaccine different from a preventive HIV vaccine?

A preventive HIV vaccine is given to people who do **not** have HIV, with the goal of preventing HIV infection in the future. The vaccine teaches the person's immune system to recognize and effectively fight HIV in case the virus ever enters the person's body. To learn more, read the HIVinfo What is a Preventive HIV Vaccine? fact sheet.

A therapeutic HIV vaccine is given to people who **already** have HIV. The goal of a therapeutic HIV vaccine is to strengthen a person's immune response to the HIV that is already in the person's body.

Where can a person get more information about clinical trials studying therapeutic HIV vaccines?

A list of clinical trials on therapeutic HIV vaccines is available from the database of ClinicalTrials.gov study summaries. Click on the title of any trial in the list to see more information about the study.

If you are interested in participating in a vaccine study, you can also contact the National Institutes of Health Vaccine Research Center by calling 866-833-LIFE (5433) or by emailing vaccines@nih.gov. To learn more, read the HIVinfo fact sheet on HIV and AIDS Clinical Trials.

This fact sheet is based on information from the following sources:

From the National Institute of Allergy and Infectious Diseases:

- HIV Vaccine Development
- Sustained ART-Free HIV Remission

From the HIV Vaccine Trials Network:

- How Vaccines Work

Also see the HIV Source collection of HIV links and resources.

What is a Preventive HIV Vaccine?

Key Points

- A preventive HIV vaccine is given to people who do not have HIV, with the goal of preventing HIV infection in the future.
- Currently, no preventive HIV vaccines have been approved by the U.S. Food and Drug Administration (FDA), but research is underway. You must be enrolled in a clinical trial to receive a preventive HIV vaccine.

What is a preventive HIV vaccine?

A preventive HIV vaccine is given to people who do not have HIV, with the goal of preventing HIV infection in the future. The vaccine teaches the person's immune system to recognize and effectively fight HIV in case the person is ever exposed to HIV.

Are there any FDA-approved preventive HIV vaccines?

Currently, no preventive HIV vaccines have been approved by the U.S. Food and Drug Administration (FDA), but research is underway. You must be enrolled in a clinical trial to receive a preventive HIV vaccine.

How is a preventive HIV vaccine different from a therapeutic HIV vaccine?

While a preventive HIV vaccine is given to people who do **not** have HIV, a therapeutic HIV vaccine is given to people who **already** have HIV. The goal of a therapeutic HIV vaccine is to strengthen a person's immune response to the HIV that is already in the person's body. Researchers are exploring the use of therapeutic HIV vaccines:

- To slow down the progression of HIV infection
- To eliminate the need for antiretroviral therapy (ART) while keeping undetectable levels of HIV

To learn more, read the HIVinfo What is a Therapeutic HIV Vaccine? fact sheet.

Can a person get HIV from a preventive HIV vaccine?

No, a person cannot get HIV from a preventive HIV vaccine. The preventive HIV vaccines being studied in clinical trials do not contain HIV. Of the approximately 30,000 people who have participated in HIV vaccine studies around the world in the last 25 years, no one has gotten HIV from any of the vaccines tested.

Why is a preventive HIV vaccine important?

Treatment options for HIV have improved a lot over the last 30 years. But HIV medicines can have side effects, can be expensive, and can be hard to access in some countries. Also, some people may develop drug resistance to certain HIV medicines and then must change medicines.

Using condoms correctly and taking pre-exposure prophylaxis (PrEP) can help prevent HIV transmission. But researchers believe a preventive HIV vaccine will be the most effective way to completely end new HIV infections.

What research is being done on preventive HIV vaccines?

Some of the areas of interest being studied in clinical trials include:

- The safety of preventive vaccines.
- Whether a preventive vaccine protects against HIV infection.
- Whether a preventive vaccine controls HIV if a person gets HIV while enrolled in a study. (It is possible for someone to get HIV through sexual contact or from sharing drug injection equipment while they are participating in a clinical trial. But a person cannot get HIV from the HIV vaccine being tested.)
- The immune responses that occur in people who receive a preventive vaccine.
- Different ways of giving preventive vaccines, such as using a needle and syringe versus a needle-free device.

Where can a person get more information about clinical trials studying preventive HIV vaccines?

A list of clinical trials on preventive HIV vaccines is available from the database of ClinicalTrials.gov study summaries. Click on the title of any trial in the list to see more information about the study.

If you are interested in participating in a vaccine study, you can also contact the National Institutes of Health Vaccine Research Center by calling 866-833-LIFE (5433) or by emailing vaccines@nih.gov.

To learn more, read the HIVinfo fact sheet on HIV and AIDS Clinical Trials.

This fact sheet is based on information from the following sources:

From the National Institute of Allergy and Infectious Diseases:

- HIV Vaccine Development

From the HIV Vaccine Trials Network (HVTN):

- How Vaccines Work
- HIV Vaccine Myths and Facts
- HVTN Trials

Also see the HIV Source collection of HIV links and resources.

HIV and AIDS Clinical Trials

Key Points

- A clinical trial is a research study done to evaluate new medical approaches in people. HIV and AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV and AIDS.
- Examples of HIV and AIDS clinical trials underway include studies of new HIV medicines, studies of vaccines to prevent or treat HIV, and studies of medicines to treat infections related to HIV and AIDS.
- The benefits and possible risks of participating in an HIV and AIDS clinical trial are explained to study volunteers before they decide whether to participate in a study.
- Use the find a study search feature on ClinicalTrials.gov to find HIV and AIDS studies looking for volunteer participants. Some HIV and AIDS clinical trials enroll only people who have HIV. Other studies enroll people who do not have HIV.

What is a clinical trial?

A clinical trial is a research study that evaluates new medical approaches in people. These approaches include:

- new medicines or new combinations of medicines
- new medical devices or surgical procedures
- new ways to use an existing medicine or device
- new ways to change behaviors to improve health

Clinical trials are conducted in several phases to determine whether new medical approaches are safe and effective in people. Results from a Phase 1 Trial, Phase 2 Trial, and Phase 3 Trial are used to determine whether a new drug should be approved for sale in the United States. Once a new drug is approved, researchers continue to track its safety in a Phase 4 Trial.

Interventional trial and observational trial are two main types of clinical trials.

What is an HIV and AIDS clinical trial?

HIV and AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV and AIDS. Every HIV medicine was first studied through clinical trials.

Examples of HIV and AIDS clinical trials include:

- studies of new medicines to prevent or treat HIV and AIDS
- studies of vaccines to prevent or treat HIV
- studies of medicines to treat infections related to HIV and AIDS

Can anyone participate in an HIV and AIDS clinical trial?

It depends on the study. Some HIV and AIDS clinical trials enroll only people who have HIV. Other studies include people who do not have HIV.

Participation in an HIV and AIDS clinical trial may also depend on other factors, such as age, gender, HIV treatment history, or

Participation in an HIV and AIDS clinical trial may also depend on other factors, such as age, gender, HIV treatment history, or other medical conditions.

What are the benefits of participating in an HIV and AIDS clinical trial?

Participating in an HIV and AIDS clinical trial can provide benefits. For example, many people participate in HIV and AIDS clinical trials, because they want to contribute to HIV and AIDS research. They may have HIV or know someone who has HIV.

People with HIV who participate in an HIV and AIDS clinical trial may benefit from new HIV medicines before they are widely available. HIV medicines being studied in clinical trials are called investigational drugs. To learn more, read the HIVinfo What is an Investigational HIV Drug? fact sheet.

Participants in clinical trials can receive regular and careful medical care from a research team that includes doctors and other health professionals. Often the medicines and medical care are free of charge.

Sometimes people get paid for participating in a clinical trial. For example, they may receive money or a gift card. They may be reimbursed for the cost of meals or transportation.

Are HIV and AIDS clinical trials safe?

Researchers try to make HIV and AIDS clinical trials as safe as possible. However, volunteering to participate in a study testing an experimental treatment for HIV can involve risks of varying degrees. Most volunteers do not experience serious side effects; however, potential side effects that may be serious or even life-threatening can occur from the treatment being studied.

Before enrolling in a clinical trial, potential volunteers learn about the study in a process called informed consent. The process includes an explanation of the possible risks and benefits of participating in the study.

Once enrolled in a study, people continue to receive information about the study through the informed consent process.

If a person decides to participate in an HIV and AIDS clinical trial, will their personal information be shared?

The privacy of study volunteers is important to everyone involved in an HIV and AIDS clinical trial. The informed consent process includes an explanation of how a study volunteer's personal information is protected.

How can one find an HIV and AIDS clinical trial looking for volunteer participants?

There are several ways to find an HIV and AIDS clinical trial looking for volunteer participants.

- Use the find a study search feature on ClinicalTrials.gov to find HIV and AIDS studies looking for volunteer participants.
- Call a Clinical Info health information specialist at 1-800-448-0440 or email ContactUs@HIVinfo.NIH.gov.
- Join ResearchMatch, which is a free, secure online tool that makes it easier for the public to become involved in clinical trials.

This fact sheet is based on information from the following sources:

From the National Institutes of Health (NIH):

- NIH Clinical Research Trials and You: The Basics

From the National Library of Medicine:

- Learn About Clinical Studies

Also see the HIV Source collection of HIV links and resources.