



U.S. ANTIRETROVIRAL THERAPY GUIDELINES

WHY DO THE GUIDELINES KEEP CHANGING?

We keep learning more about the best way to fight HIV. In 1998, the US Department of Health and Human Services created a panel of physicians, researchers, and consumers to develop treatment guidelines. They constantly review HIV research results. The guidelines are updated at least once each year. This fact sheet reflects the guidelines as of January 2017.

NOTE: These are guidelines, not rules. Patients should receive individualized care from a health care provider with experience treating HIV infection. **The full text of these guidelines is available on the Internet at <http://www.aidsinfo.nih.gov/>**

VIRAL LOAD AND CD4 CELL TESTING

Viral load and CD4 cell tests provide critical information for decisions on antiretroviral therapy (ART). Fact Sheet 124 has more information on CD4 cell tests and Fact Sheet 125 covers viral load testing.

Viral load should be tested:

- At the start of HIV care, and before starting or changing medications. This provides a reference value;
- About 2 to 8 weeks after starting or changing medications. This shows whether the new drugs are working;
- Every 1 or 2 months until the viral load is suppressed, and every 3 to 4 months during the first 2 years of treatment.
- After 2 years of viral suppression, viral loads may be monitored every 6 months.
- Viral suppression (or "undetectable" viral load) means that there is not enough virus in a person's body for the test to find and count.
- Virologic failure is defined as a confirmed viral load over 200 copies after 6 months of treatment.

CD4 cell counts should be done:

- When someone first tests HIV-positive.
- Every 3-6 months before starting ART, in case of ART not being started right away.
- Three months after starting ART.
- Every 3-6 months to monitor the strength of the immune system during the first 2 years of ART.
- Every 12 months after 2 years of ART if the viral load is undetectable and the CD4 count is between 300 and 500.
- Optional if the CD4 count is above 500 and the viral load is undetectable after 2 years.

RESISTANCE TESTING

Viral resistance testing helps health care providers choose the most effective drugs. See

Fact Sheet 126 for more information. Resistance testing is recommended for patients starting therapy, when viral load is not controlled by new medications, or when it "breaks through" a regimen that used to work. The guidelines recommend resistance testing before starting ART, to help in choosing the first ART regimen. This can show if the person got infected with drug-resistant virus.

OTHER LABORATORY TESTS

The guidelines recommend using a viral tropism test (see fact sheet 129) before starting therapy with a CCR5 inhibitor. They also recommend using a genetic test, HLA-B*5701 before starting abacavir (see fact sheet 416).

WHEN TO START TREATMENT

Treatment is recommended for all people living with HIV, regardless of CD4 count.

Regardless of CD4 count, treatment is strongly recommended for all pregnant patients, patients with HIV-associated nephropathy (a kidney disorder), or those who need treatment for hepatitis B.

GOALS OF THERAPY

The guidelines list the following goals for HIV therapy. Treatment goals are the same for people starting therapy and those who have been on therapy for a long time:

- Reduce viral load as much as possible for as long as possible
- Restore or preserve the immune system
- Reduce sickness and death due to HIV
- Prolong the duration and quality of life
- Prevent HIV transmission

The following tools are suggested to help achieve these goals:

- Choosing a first ART regimen
- Maximizing adherence: Helping the patient take medications correctly

WHAT DRUGS SHOULD BE USED FIRST?

The guidelines recommend 6 ART regimens for people starting anti-HIV treatment. Five of the 6 regimens use an HIV integrase inhibitor:

- Dolutegravir/abacavir/lamivudine (Triumeq)
- Dolutegravir (Tivicay) + tenofovir AF/emtricitabine (Descovy) OR tenofovir DF/emtricitabine (Truvada)
- Elvitegravir/cobicistat/tenofovir AF/emtricitabine (Genvoya)
- Elvitegravir/cobicistat/tenofovir DF/emtricitabine (Stribild)
- Raltegravir (Isentress) + Descovy OR Truvada

One regimen uses a protease inhibitor:

- Darunavir (Prezista) + ritonavir (Norvir) + Descovy OR Truvada

Several other combinations are categorized as "alternative" or "other" regimens, including previously recommended efavirenz/tenofovir DF/emtricitabine (Atripla), rilpivirine/tenofovir DF/emtricitabine (Complera), and atazanavir (Reyataz) + Norvir + Truvada. These regimens have possible disadvantages compared with the recommended regimens, or have less study data.

Descovy (alone and in coformulated tablets) has also been added as an option in several recommended and alternative regimens, based on data showing that regimens containing Descovy are as effective as Truvada-containing regimens, with more favorable effects on markers of bone and kidney health.

FACTORS TO CONSIDER IN CHOOSING INITIAL ART

The guidelines recommend considering pre-treatment

- Viral load
- CD4 count
- HIV resistance test results
- HLA-B*5701 status
- Patient preferences and anticipated adherence

Selection should also consider the patient's

- Cardiovascular disease
- Kidney, liver, and bone disease
- Mental health
- Neurologic disease
- Drug addiction treatment
- Pregnancy or pregnancy potential
- Co-infection with hepatitis B virus, hepatitis C virus, and tuberculosis

ADHERENCE

Taking ART correctly, every day, is critical for the medications to work; this is called adherence (see fact sheet 405). The guidelines recommend involving the patient in ART selection, assessing adherence at every clinic visit, and identifying the type and reasons for non-adherence.

OTHER PARTS OF THE GUIDELINES

The guidelines discuss other topics, including virologic failure, poor CD4 recovery, regimen switching, and the discontinuation or interruption of treatment.

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