Association for the Advancement of Blood & Biotherapies

# Implementation of the Updated AABB DHQ v4.0 Medication Deferral List

## Recently FDA approved injectable PrEP medication:

**Yeztugo® (lenacapavir)**

**July 9, 2025**

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# I. Background:

On June 18, 2025, the Food and Drug Administration (FDA) approved YEZTUGO® (lenacapavir), an injectable HIV-1 capsid inhibitor, for use as pre-exposure prophylaxis (PrEP) in adults and adolescents. YEZTUGO® is the first and only PrEP option available in the United States that requires administration just twice a year.

In the May 2023 FDA guidance, Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, FDA recommended a two-year deferral following the most recent injection of a medication to prevent HIV infection. This recommendation was based on the pharmacokinetics of the FDA approved long-acting antiviral drug, Apretude (cabotegravir) and referenced the donor deferral recommendation made by the AABB Transfusion-Transmitted Diseases (TTD) Committee in the September 2022 AABB Association Bulletin #22-03.

Following the recent FDA approval of YEZTUGO® (lenacapavir) the following actions were taken:

1. The TTD Committee formed a Working Group to evaluate and recommend a donor deferral period based on the pharmacokinetics of the new medication.
2. Following careful review of the existing data, the Working Group recommended maintaining the current donor history questions and associated deferrals and the addition of Yeztugo (Lenacapavir) to the Donor History Questionnaire v4.0 (DHQ) Medication Deferral List (MDL).
3. The TTD Committee recommendation (Section II, below) was next reviewed and approved by the entire TTD Committee and sent to the AABB Donor History Task Force (DHTF) for consideration.
4. The DHQ v4.0 MDL was then updated by the DHTF to include YEZTUGO® (lenacapavir) (Section III, below).

AABB would like to sincerely thank the TTD Committee and the DHTF for their work, dedication and continued efforts to ensure that blood remains safe and available for the patients we serve.

# II. AABB Transfusion Transmitted Disease Committee Donor Deferral Recommendation:

Lenacapavir as PrEP - Transfusion Transmitted Diseases Committee Donor deferral Recommendation

**Lenacapavir** (brand name Yeztugo®) is a, long-acting injectable medication[1] recently approved by the U.S. Food and Drug Administration (FDA) for use as subcutaneous pre-exposure prophylaxis (PrEP) to prevent HIV-1 infection in adults and adolescents at risk.[2] It is the only PrEP option that provides six months of protection per single injection, which can foster very high levels of adherence, enhancing its protective effectiveness.[3] An intramuscular preparation is being studied for annual administration as PrEP but is yet to be approved.

Lenacapavir is a first-in-class HIV capsid inhibitor, targeting the protein shell (capsid) of the virus, and interfering with multiple essential steps in viral replication and maturation. By disrupting the capsid, lenacapavir prevents HIV from infecting immune cells and stops the formation of new, mature virus particles.[1, 4] It received a prior therapeutic approval (as Sunlenca®) for treatment-experienced HIV infected people with resistance to other antiretroviral drugs.

Approval as PrEP is based on two randomized, controlled trials of lenacapavir for HIV infection prevention in comparison to persons not taking PrEP. PURPOSE 1, among cisgender sub-Saharan African women, demonstrated 100% efficacy.[5] PURPOSE 2, a multinational study among cisgender men, transgender women and men, and nonbinary individuals who have sex with men demonstrated 96% efficacy.[6] Lenacapavir was also significantly more effective at HIV prevention in PURPOSE 2 compared to oral PrEP (emtricitabine-tenofovir disoproxil fumarate), and some analyses suggest it is superior, particularly when there are barriers to adherence to daily oral approaches.[7]

The AABB Donor History Questionnaire (DHQ) Medication Deferral List and the AABB Standards for Blood Banks and Transfusion Services require blood donor deferral for receipt of drugs to treat and prevent HIV infection.[8] Donors having received PrEP orally are deferred for 3 months, recipients of injectable cabotegravir (Apretude®) are deferred for 2 years, and recipients of HIV treatment are permanently deferred. These deferrals are predicated on the pharmacokinetics of the agents and the risk that they can alter the dynamics of donor test evolution following a breakthrough infection, potentially leading to false-negative test results and increasing the risk of transfusing an infectious blood product.

TTD has considered these issues in order to recommend a deferral period for lenacapavir PrEP recipients. Breakthrough infections are exceedingly rare, so detailed studies of test performance, if and when they occur, are not available to date.

A long-acting, early viral inhibition (LEVI) effect, as associated with cabotegravir and associated with difficult viral detection, has not been described with lenacapavir.[7] The

lenacapavir terminal half-life is 8-12 weeks (similar to cabotegravir at 5.6-11.5 weeks) In light of its potency, this permits twice yearly dosing with lenacapavir for ongoing HIV protection.[9] Pharmacokinetic studies suggest its plasma concentration falls below the protein adjusted 95% effective inhibitory concentration ($paEC_{95}$) (≤4 nG/mL)[10] by approximately 48 weeks after the administered dose[1], with no accumulation based on limited studies. Extended PK studies beyond 1-2 years are not yet publicly available. Lenacapavir may remain detectable beyond 2 years, (as is the case with cabotegravir) but should be below effective antiviral levels well before that. Lenacapavir use during pregnancy was not associated with drug-associated risk for miscarriage, or adverse maternal or fetal outcomes. Residual drug levels in blood products are therefore not a material concern in pregnant women who may receive blood products. Accordingly, we suggest that a 2-year deferral should be recommended and can be amended as extended studies and clinical experience accrue (as was the case with cabotegravir). A consistent deferral period for the two injected PrEP drugs is an operationally safe and simple approach.

In light of these considerations TTD recommends maintaining the current donor history questions and associated deferrals:

- In the **past 3 months**, have you taken any medication by mouth to prevent an HIV infection?
- In the **past 2 years**, have you received an injection or shot to prevent an HIV infection?

**References:**

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## III. AABB DHQ v4.0 Medication Deferral List

As described above, the DHQ v4.0 MDL has been updated by the DHTF to include YEZTUGO® (Lenacapavir). This addition can be found under the section labeled, **HIV prevention (also known as PrEP or PEP)**, as illustrated in the pdf on page 6 of this Toolkit.

The downloadable PDF and Word versions of the updated MDL v4.0 can be found on the AABB Blood Donor History Questionnaires page and at these links copied here for your convenience:

- AABB Blood DHQ/aDHQ v4.0 Medication Deferral List – updated July 2025 Yeztugo (Lenacapavir) PDF
- AABB Blood DHQ/aDHQ v4.0 Medication Deferral List – updated July 2025 Yeztugo (Lenacapavir) Word

This minor addition to the MDL does not require a version update.

# **Medication Deferral List** (DHQ/aDHQ v4.0)

**DO NOT STOP taking medications prescribed by your doctor in order to donate blood. Donating while taking these drugs could have a negative effect on your health or on the health of the recipient of your blood. PLEASE TELL US IF YOU:**

| ARE BEING TREATED WITH ANY OF THE FOLLOWING TYPES OF MEDICATIONS: | OR HAVE TAKEN: | | WHICH IS ALSO CALLED: | ANYTIME IN THE LAST: |
|---|---|---|---|---|
| **Antiplatelet agents (usually taken to prevent stroke or heart attack)** | Feldene | | piroxicam | **2 Days** |
| | Effient | | prasugrel | **3 Days** |
| | Brilinta | | ticagrelor | **7 Days** |
| | Plavix | | clopidogrel | **14 Days** |
| | Ticlid | | ticlopidine | |
| | Zontivity | | vorapaxar | **1 Month** |
| **Anticoagulants or "blood thinners" (usually taken to prevent blood clots in the legs and lungs and to prevent strokes)** | Arixtra | | fondaparinux | **2 Days** |
| | Eliquis | | apixaban | |
| | Fragmin | | dalteparin | |
| | Lovenox | | enoxaparin | |
| | Pradaxa | | dabigatran | |
| | Savaysa | | edoxaban | |
| | Xarelto | | rivaroxaban | |
| | Coumadin, Warfilone, Jantoven | | warfarin | **7 Days** |
| | Heparin, low-molecular-weight heparin | | | |
| **Acne treatment** | Accutane Amnesteem Absorica Claravis Myorisan Sotret Zenatane | | isotretinoin | **1 Month** |
| **Multiple myeloma** | Thalomid<br>Revlimid | | thalidomide<br>lenalidomide | |
| **Rheumatoid arthritis** | Rinvoq | | upadacitinib | |
| **Hair loss remedy** | Propecia | | finasteride | |
| **Prostate symptoms** | Proscar | | finasteride | |
| | Avodart<br>Jalyn | | dutasteride | **6 Months** |
| **Immunosuppressant** | Cellcept | | mycophenolate mofetil | **6 Weeks** |
| **Hepatitis exposure** | Hepatitis B Immune Globulin | | HBIG | **3 Months** |
| **HIV prevention (also known as PrEP or PEP)** | Any medication taken by mouth (oral) to prevent HIV. | Truvada | emtricitabine and tenofovir disoproxil fumarate | |
| | | Descovy | emtricitabine and tenofovir alafenamide | |
| | Injectable HIV prevention | Apretude<br>Yeztugo | cabotegravir<br>lenacapavir | **2 Years** |
| **Basal cell skin cancer** | Erivedge<br>Odomzo | | vismodegib<br>sonidegib | **2 Years** |
| **Relapsing multiple sclerosis** | Aubagio | | teriflunomide | |
| **Rheumatoid arthritis** | Arava | | leflunomide | |
| **Psoriasis** | Soriatane | | acitretin | **3 Years** |
| | Tegison | | etretinate | **Ever** |
| **HIV treatment** | Any medication to treat HIV. May also be called antiretroviral therapy (ART) | | | |
| **Experimental medication** | | | | **As defined by the medical director** |

## IV. Implementation and FDA Reporting

The AABB DHQ v4.0 User Brochure provides the following information on implementation and FDA reporting:

> *"As updates are required, the DHTF will make changes to the MDL that will be announced in AABB publications prior to posting of the new version on the AABB website. Blood collection establishments may either replace their current MDL with the AABB update or modify their own materials. As stated by FDA at the time of acceptance, under 21 CFR 601.12(d),* ***licensed blood establishments are required to report this minor change and its implementation date in their next annual report. Updates to the MDL should be implemented as defined in blood collection establishment SOPs and soon as reasonably possible****."*

**Questions?** Email Regulatory@aabb.org