Stavudine

NOT RECOMMENDED AS AN ESSENTIAL MEDICINE

Section: 6. Anti-infective medicines > 6.4. Antiviral medicines > 6.4.2. Antiretrovirals > 6.4.2.1. Antiretrovirals > Nucleoside/Nucleotide reverse transcriptase inhibitors

EMLc ATC codes: J05AF04

Indication	Human immunodeficiency virus disease without mention of tuberculosis or malaria, clinical stage unspecified ICD11 code: 1C62.Z
INN	Stavudine
Medicine type	Chemical agent
List type	Core
Formulations	**Oral > Liquid:** 5 mg per 5 mL powder for oral solution **Oral > Solid:** 15 mg ; 20 mg ; 30 mg
EML status history	First added in 2002 (TRS 914) Changed in 2007 (TRS 950) Changed in 2009 (TRS 958) Removed in 2017 (TRS 1006)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Stavudine
DrugBank	Stavudine

Expert Committee recommendation

Recalling the recommendation from the 2015 meeting, the Expert Committee recommended the deletion from the EML and EMLc of abacavir oral liquid 100 mg/5 mL, efavirenz capsules 50 mg, 100 mg and 200 mg, stavudine capsules 15 mg, 20 mg and 30 mg and powder for oral liquid 5 mg/mL, and zidovudine capsules 100 mg. Noting the advice from the WHO Department of HIV/AIDS about the continued recommendation in current WHO guidelines for use of lamivudine oral liquid for the treatment of newborns, the Expert Committee recommended that it be deleted from the EML but retained on the EMLc. The Committee considered the rationale behind the new proposals to delete atazanavir, lamivudine + nevirapine + stavudine, nevirapine and saquinavir formulations to be reasonable and therefore recommended deletion of the items as proposed. In the case of zidovudine solution for IV infusion injection, the Committee noted that, although not included in current WHO HIV guidelines, it is still recommended by a number of other international guidelines for HIV-positive women who have viral loads greater than 1000 copies/mL and are therefore considered to be at high risk for maternal-to-newborn HIV transmission. The Committee therefore recommended zidovudine solution for IV infusion injection be retained on the EML for the subset of HIV-positive pregnant patients who are at high risk of transmitting the infection to their newborns.

Background

The 2015 Expert Committee recommended deletion from the EML and EMLc in 2017 of stavudine capsules and powder for oral liquid formulations without further discussion unless an application was received to support their retention (1). WHO's Department of HIV/AIDS continues to support the deletion of these medicines from the EML and EMLc in 2017.

Public health relevance

N/A

Benefits

The rationale provided in the application for the requested new deletions fell into three categories, described below and summarized in the table (refer to TRS 1006): ■ Category 1: exclusion of the medicine as a therapeutic option in current guidelines. The medicine is in the current EML/EMLc and is not recommended as a therapeutic option in the 2016 WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. ■ Category 2: exclusion of the formulation as a therapeutic option in current guidelines. Dose in the current EML is not aligned with the recommended dosing in the 2016 WHO Consolidated guidelines. ■ Category 3: provide alignment with the optimal Formulary of the Interagency Task Team (IATT) on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Their Children (3).

Harms

N/A

Additional evidence

N/A

Cost / cost effectiveness

N/A

WHO guidelines

The proposed deletions are in alignment with recommendations in the 2016 WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection and with the IATT Paediatric ARV Formulary, revised in 2016.

Availability

N/A

Other considerations

No applications were received to support retention of stavudine.

Implementation considerations

N/A

1. The selection and use of essential medicines. Report of the WHO Expert Committee, 2015 (including the 19th WHO Model List of Essential Medicines and the 5th WHO Model List of Essential Medicines for Children). Geneva: World Health Organization; 2015 (WHO Technical Report Series, No. 994).
2. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, second edition. Geneva: World Health Organization; 2016 (http://www.who.int/hiv/pub/arv/arv-2016/en/, accessed 19 January 2017).
3. Policy Brief: IATT Paediatric ARV Formulary and Limited-Use List: 2016 update. Interagency Task Team (IATT) for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children; 2016 (http://emtct-iatt.org/wp-content/uploads/2016/10/Updated-Ped-ARV-Formulary-List-5-Sept-2016-1.pdf, accessed 19 January 2017).

