Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice Number: Advice No: 2213 – July 2013

Tenofovir disoproxil (as fumarate) (Viread®) 123 mg, 163 mg, 204 mg and 245 mg film-coated tablets and 33 mg/g granules

Limited submission by Gilead Sciences Ltd

Recommendation of the All Wales Medicines Strategy Group

Tenofovir disoproxil (as fumarate) (Viread®) film-coated tablets are recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of HIV-1-infected adolescent and paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years (245 mg tablets) and aged 6 to < 12 years who weigh from 17 kg to less than 22 kg (123 mg tablets), 22 kg to less than 28 kg (163 mg tablets) and 28 kg to less than 35 kg (204 mg tablets).

Tenofovir disoproxil (as fumarate) (Viread®) 33 mg/g granules are recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with NRTI resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate.

The choice of tenofovir disoproxil to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1643), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the

views of patients/patient carers (where available) and the lay member perspective.

The All Wales Therapeutics and Toxicology Centre (AWTTC) reviewed this appraisal recommendation in December 2022. No new evidence was identified that is likely to significantly affect the current recommendation. Therefore, this recommendation has been transferred to AWMSG's static list of medicine recommendations.