Enclosure no:	2/AWMSG/0723
Agenda item no:	6 – NMG Preliminary Appraisal Recommendation Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®)
Author:	New Medicines Group
Contact:	Tel: 029 218 26900 E-mail: awttc@wales.nhs.uk

Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®) 200 mg/25 mg film-coated tablets

Indication under consideration:

Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®) for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men, including adolescents (with body weight at least 35 kg).

Marketing authorisation holder: Gilead Sciences Ltd

Date: Wednesday 7 June 2023

NMG advice to AWMSG:

Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®) is not recommended for use within NHS Wales for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk men who have sex with men, including adolescents (with body weight at least 35 kg).

The case for cost-effectiveness has not been proven.

Key factor(s) influencing the recommendation:

- No health economic model was provided.
- No published cost effectiveness study was found to inform the decision of whether Descovy[®] for PrEP is cost-effective versus best standard care.

Additional note(s):

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

Statement of use: No part of this preliminary recommendation may be reproduced without the whole recommendation being quoted in full and cited as:

New Medicines Group Preliminary Appraisal Recommendation Emtricitabine/tenofovir alafenamide (as fumarate) (Descovy®). Reference number 2566. June 2023. People who are currently receiving emtricitabine/tenofovir alafenamide
(as fumarate) (Descovy®) for the indication stated above should have the
option to continue their therapy until they and their clinicians consider it
appropriate to stop.

In reaching the above recommendation NMG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2566), which includes the AWMSG Secretariat Assessment Report (ASAR) and the applicant company's response to the ASAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

Statement of use: No part of this preliminary recommendation may be reproduced without the whole recommendation being quoted in full and cited as: