All Wales Therapeutics and Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

AWMSG Secretariat Assessment Report – Limited submission

Emtricitabine/tenofovir alafenamide (Descovy®▼) 200 mg/10 mg 200mg/25mg film-coated tablets

Company: Gilead Sciences Ltd

Licensed indication under consideration:
Emtricitabine/tenofovir alafenamide (Descovy®▼) is indicated in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1).

Date of licence: 21 April 2016

Comparator(s)

The comparator included in the company submission was emtricitabine/tenofovir disporoxil fumarate (Truvada®)

Limited submission details

- Anticipated usage in NHS Wales is considered to be of minimal budgetary impact.
- Estimated small difference in cost compared to comparator.

Clinical effectiveness

- Descovy®▼ differs from Truvada® in having tenofovir alafenamide in place of tenofovir disoproxil fumarate. Tenofovir alafenamide and tenofovir disoproxil fumarate are both prodrugs which metabolise to generate tenofovir. Effective therapeutic concentrations of tenofovir in lymphoid cells are obtained from a much smaller dose of tenofovir alafenamide than tenofovir disoproxil fumarate, minimising systemic exposure (90% lower plasma concentrations versus a 245 mg oral dose of tenofovir disoproxil fumarate) and reducing unwanted side effects.

- The components of Descovy®▼ have been evaluated in a large clinical trial programme (> 3,400 patients) involving a patient population of treatment-naïve adults and adolescents, and treatment-experienced adult patients including patients with mild-to-moderate renal impairment.

- High rates of virological suppression (HIV-1 RNA < 50 copies/ml) were reported in patients switching to Descovy®▼ plus a third agent (n = 333) compared with continuing on Truvada® plus a third agent (n = 330) (94.3% versus 93.0%, respectively).

- Descovy®▼ has favourable bone mineral density outcomes (BMD), with significant improvements in BMD (hip and spine) and bone biomarkers among treatment-experienced individuals switching to Descovy®▼, plus a third agent compared with those continuing on Truvada®.

- Descovy®▼ plus a third agent has demonstrated a statistically significantly favourable renal safety profile compared to Truvada® and does not require additional renal monitoring associated with tenofovir disoproxil fumarate containing regimens.

Budget impact

- The company estimate the number of patients eligible to receive Descovy®▼ to be 226 in year one based on the number of patients with HIV in Wales, annual incidence figures, the proportion of patients who received antiretroviral therapy treatment in Wales (2014) and the annual HIV mortality rate. The company estimate that the number of eligible patients will increase to 420 in year five due to increased uptake.

- If emtricitabine/tenofovir disporoxil fumarate (Truvada®) is displaced, the introduction of emtricitabine/tenofovir alafenamide (Descovy®▼) would be cost neutral.

Additional information

- AWTTC is of the opinion that, if recommended, emtricitabine/tenofovir alafenamide (Descovy ®▼) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

- The company anticipate that emtricitabine/tenofovir alafenamide (Descovy®▼) may be supplied by a home healthcare provider.

Evidence search

Date of evidence search: 19th May 2016.
Date of range of evidence search: No date limits were applied to database searches.

Further information

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTC at AWTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. emtricitabine/tenofovir alafenamide(Descovy ®▼) 200 mg/10 mg, 200mg/25mg film-coated tablets. Reference number: 2771. September 2016.