Enc 10 Appx 3

Clinical Expert Summary

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

Emtricitabine/tenofovir alafenamide (Descovy®▼) 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).

1.Existing guidelines

Reference was made to guidelines from the British HIV Association (BHIVA) and Children's HIV Association (CHIVA).

2. Disease prevalence/incidence

An expert reported there are 14 children with HIV, 10 of which are > 12 years of age.

3. Current treatment options

- Triumeq
- Truvada/ Darunavir/ritonavir or Truvada/Atazanavir/ritonavir
- Eviplera
- Stribild

BHIVA guidelines recommend the above choices, however Atripla is still widely prescribed in stable patients. The trend however is to offer a switch off Atripla, to one of the above regimens, to decrease short term and longer term side-effects.

4. Unmet needs

Tenofovir disoproxil based regimens, including Truvada, are not recommended in patients with moderate renal impairment (starting treatment is recommended in patients with CrCl>70ml/min, and switching off treatment if CrCl <50ml/min). Therefore there are a proportion of patients who would benefit from access to a tenfovir alafenamide regimen (Descovy), which can be prescribed for patients with CrCl>30ml/min. This group of patients are increasing as HIV is a manageable chronic disease and therefore patients are aging with HIV. Therefore Descovy would be an extremely important new medication for this group of patients that could enable them to achieve HIV virological suppression.

5. Knowledge of product in given indication

Tenofovir alafenamide is less toxic renally, which enables it to be prescribed for a wider range of patients, including those with moderate renal dysfunction (CrCL > 30 ml/min). It also requires no additional renal monitoring. There are also 2 strengths of Descovy, dependent upon the co-administered 3rd agent to also decrease potential renal toxicity further. This is advantageous when co-prescribed with a protease inhibitor, which increase tenofovir alafenamide levels. Descovy would potentially be used in preference to Truvada for most naive patients starting treatment.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to emtricitabine/tenofovir alafenamide for the indication under consideration.