



AWMSG Secretariat Assessment Report – Limited submission

Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya[®]▼) 150 mg/150 mg/200 mg/10 mg

Company: Gilead Sciences Ltd

Licensed indication under consideration:

Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya[®]▼) for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus 1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.

Marketing authorisation date: 19 November 2015

Comparator(s)

Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (Stribild[®]▼).

Limited submission details

- Significant new formulation which has a pro-rata or lower cost per treatment
- Anticipated minimal budgetary impact in NHS Wales
- Genvoya[®]▼ differs from Stribild[®]▼ in having tenofovir alafenamide (TAF) in place of tenofovir disoproxil fumarate (TDF). TAF and TDF are however both prodrugs which metabolise to generate tenofovir. Effective therapeutic concentrations of tenofovir in lymphoid cells are obtained from a much smaller dose of TAF than TDF.

Clinical effectiveness

- In two large phase III studies, HIV-1 infected treatment-naive patients who received Genvoya[®]▼ showed non-inferiority in viral suppression and improvements in renal function and bone mineral density (BMD) measurements in comparison to patients who received Stribild[®]▼. Similarly, in a large phase III study treatment-experienced patients who switched from other antiretroviral regimens (all containing TDF) to Genvoya[®]▼ maintained viral suppression and showed improved BMD and (for patients previously receiving boosted regimens) improved renal function.
- Smaller studies were carried out in three further sets of patients with HIV-1 infection: treatment-naive adolescents (mean age 15 years), patients with mild to moderate renal impairment and patients co-infected with Hepatitis B virus. Results were supportive of the larger studies, showing high rates of virological suppression and improvements in renal and BMD measurements.
- Compared to Welsh demographics the patients in the studies had lower, but still significant proportions of white populations.
- Genvoya[®]▼ showed no new adverse events compared to Stribild[®]▼. There was evidence of less negative effects on renal function and BMD associated with use of Genvoya[®]▼ in comparison to Stribild[®]▼.

- The use of TDF in adolescents is restricted because of safety concerns in growing adolescents, including effects on bone mineralisation. Due to limited data the Committee for Medicinal Products for Human Use recommends specific monitoring of adolescents in their risk management plan.

Budget impact

- The company has used 2014 HIV prevalence and incidence data for Wales to estimate that the number expected to receive Genvoya[®] will range from 15 patients in year one to 112 patients in year five.
- The company have assumed that Genvoya[®] will displace only Stribild[®]; displacement of other antiretroviral regimens has not been considered. Since the list price of Genvoya[®] is the same as the list price of Stribild[®] (£880 for a 30 tablet pack) the net budget impact based on list prices is zero for years one to five.
- [commercial in confidence data removed]

Additional information

- AWTTTC is of the opinion that, if recommended, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya[®]) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.
- The company anticipate that elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya[®]) may be supplied by a home healthcare provider.

Evidence search

Date of evidence search: 8 December 2015.

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 AWTTTC at AWTTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya[®]) 150 mg/150 mg/200 mg/10 mg. Reference number: 2248. June 2016.