AWMSG Secretariat Assessment Report – Limited submission

Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) 100 mg/300 mg/245 mg film-coated tablets

Company: Merck Sharp & Dohme Limited

Licensed indication under consideration: treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Marketing authorisation date: 3 April 2019

Comparator(s)

The comparators included in the company's submission are:

- Emtricitabine/rilpivirine/tenofovir disoproxil (Eviplera®)
- Abacavir/dolutegravir/lamivudine (Triumeq®)
- Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy®)
- Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate (Genvoya®)

Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). Eviplera® is the only comparator above containing an NNRTI (rilpivirine) and would therefore be the most likely comparator to be displaced.

Limited submission details

AWMSG appraisal criteria requires doravirine (Pifeltro®) to be recommended before Delstrigo® can be appraised as a limited submission.

The limited submission criteria were met based on:

- significant new formulation with a pro-rata or lower cost per treatment
- anticipated usage in NHS Wales is considered to be of minimal budgetary impact

Clinical effectiveness

- In a large, randomised, double-blind phase III study (DRIVE-AHEAD) Delstrigo® showed non-inferior virological efficacy compared to efavirenz/emtricitabine/ tenofovir disoproxil fumarate (Atripla®) in treatment-naive HIV-1–infected adults at 48 weeks.
- A large, randomised, open-label phase III study (DRIVE-SHIFT) showed non-inferior virological efficacy for patients who switched from a stable antiretroviral baseline regimen to Delstrigo® for 48 weeks compared to those who remained on the baseline regimen.

- AWTTC-sought clinical expert opinion was that Delstrigo® would offer an additional treatment option and offers some advantages over other NNRTI medications and so would be likely to be used in some patients in Wales, especially in those with resistance to other regimens.

Budget impact

- The company estimates that in Year 1 there are 830 patients in Wales eligible for treatment with Delstrigo® increasing to 1,118 patients in Year 5. This is based on extrapolation from HIV prevalence in 2017 and incidence data/mortality rates from 2009 to 2017 reported by Public Health England.
- The company estimated the proportion of patients taking single tablet regimens to be 35% based on company sought clinical expert advice. Based on the company's market share estimations, the company predict [commercial in confidence figure removed] patients will receive treatment with Delstrigo® in Year 1 increasing to [commercial in confidence figure removed] patients in Year 5.
- The budget impact analysis is based on Delstrigo® partly displacing all four comparators based on estimated market share of each comparator. [Commercial in confidence information removed]. This is based on the discounted WPAS price for Delstrigo® and list prices for Eviplera®, Triumeq®, Biktarvy® and Genvoya®. However Triumeq®, Biktarvy® and Genvoya® have associated confidential WPASs and the influence of these is not included in the analysis.
- To determine the influence of these WPASs the company conducted a sensitivity analysis varying a combined discount of between 5% and 95% from the total list prices for the three comparators: Triumeq®, Biktarvy® and Genvoya®. [Commercial in confidence information removed].

Additional information

- AWTTC is of the opinion that, if recommended, doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) would be appropriate for specialist only prescribing within NHS Wales for the indication under consideration.
- The company anticipates that doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) may be supplied by a home healthcare provider.

Evidence search

Date of evidence search: 30 January 2020

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. Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) 100 mg/300 mg/245 mg film-coated tablets. Reference number: 3648. September 2020.