AWMSG Secretariat Assessment Report – Limited submission

Atazanavir/cobicistat (Evotaz®▼) 300 mg/150 mg film-coated tablets

Company: Bristol-Myers Squibb Pharmaceuticals Ltd

Licensed indication under consideration:
Atazanavir/cobicistat (Evotaz®▼) in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.

Marketing authorisation date: 13 July 2015

Comparator(s)

The comparator included in the company submission was atazanavir (Reyataz®) with ritonavir (Norvir®).

Limited submission details

The limited submission criteria were met as the anticipated usage of atazanavir/cobicistat in NHS Wales is considered to be of minimal budgetary impact.

Clinical effectiveness

- Atazanavir (Reyataz®), co-administered with low dose ritonavir, is recommended as an option for use within NHS Wales for the treatment of HIV-1 infected adults and paediatric patients six years of age and older in combination with other antiretroviral medicinal products.
- Cobicistat, a pharmacokinetic enhancer, is an analogue of the protease inhibitor ritonavir which, unlike ritonavir, has no anti-retroviral activity. AWMSG has previously recommended cobicistat as an option for use as part of other fixed dose combinations.
- Clinical experts highlight that local and national guidelines currently feature atazanavir as an alternative option where other treatments are not suitable and suggest atazanavir/cobicistat would be a valuable additional option to be used when treatment with atazanavir plus ritonavir is not suitable.
- Evidence of clinical effectiveness is based on the pivotal phase III, randomised, double-blind study of the efficacy and safety of the single agents cobicistat and atazanavir versus ritonavir and atazanavir in combination with emtricitabine/tenofovir (Truvada®). Atazanavir plus cobicistat demonstrated non-inferior efficacy to that achieved by atazanavir plus ritonavir, in terms of HIV-1 RNA suppression in treatment-naïve patients with HIV-1.
- The Committee for Medicinal Products for Human Use concluded that overall, the data suggest that atazanavir/cobicistat is generally well tolerated; and, common adverse events were consistent with those expected in the patient population and the known safety profiles of the medicines.
- In a phase I, open-label, single-centre, single-dose, crossover study, atazanavir/cobicistat fixed-dose combination was found to be bioequivalent to the atazanavir and cobicistat single agents.

Budget impact

- Prevalence, incidence and mortality data for HIV infection were obtained from Welsh 2009 to 2013 data published by Public Health England. The proportion of patients receiving treatment is estimated at 1,571 in year one rising to 1,978 in year five.
- The budget impact analysis is based on atazanavir/cobicistat displacing atazanavir plus ritonavir. In year one, based on IMS data, the company estimate that of the 10.3% (162) of patients likely to receive treatment with atazanavir plus ritonavir, 0.1% (1-2) would be eligible for treatment with atazanavir/cobicistat. The eligible number of patients is expected to be constant over the five years. This is based on company sales forecast and the assumption that a large proportion of patients are already stabilised on their current therapies.
- The company estimates a budget impact of £11 in year one rising to £13 in year five. The company has also provided a sensitivity analysis based on the median market share acquired by the third agents launched in the last five years. This estimates 0.7% (11-14) would be eligible for treatment and increase the budget impact to £75 in year one rising to £94 in year five.
- Clinical experts suggest the higher number of patients would be more likely to receive the new fixed dose combination if approved.

Additional information

- AWTTC is of the opinion that, if recommended, atazanavir/cobicistat (Evotaz®▼) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.
- The company anticipate that atazanavir/cobicistat (Evotaz®▼) may be supplied by a home healthcare provider.

Evidence search

Date of evidence search: 7 September 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 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. Atazanavir/cobicistat (Evotaz®▼) 300 mg/150 mg film-coated tablets. Reference number: 2629. November 2015.