INAHTA Brief

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Title DELTYBA – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/p_3120940/fr/deltyba

Aim

Assessment of DELTYBA (delamanid) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies with a view to setting of its price by the French Healthcare Products Pricing Committee (CEPS) as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

Conclusions of Transparency Committee

Substantial clinical benefit in the indication, considering:

- Multi-drug resistant tuberculosis (MDR-TB) is a rare disease in France, which is frequently fatal. Its frequency is increasing sharply worldwide.
- This proprietary medicinal product is part of a curative treatment regimen.
- The efficacy/adverse effects ratio has still not been adequately established in clinical studies and remains to be specified in the context of the conditional marketing authorisation. However, preliminary data are reassuring at present and deemed to be satisfactory in view of the medical need.
- This proprietary medicinal product is an antibacterial agent of last resort for the treatment of patients with multi-drug resistant tuberculosis (MDR-TB), susceptible to delamanid and when the prescription of a group C agent in the WHO classification is indicated.
- At this stage of the infection, there are few therapeutic alternatives.
- Public health impact:

According to currently available data, DELTYBA is not likely to have an impact on public health in the current management of multi-drug resistant tuberculosis (MDR-TB).

Moderate Clinical Added Value (CAV III) in the management of multi-drug resistant tuberculosis, susceptible to delamanid, when the use of a WHO group C anti-tuberculosis drug is indicated and following the opinion of the mycobacteria reference centre, taking into consideration:

- the substantial medical need in multi-drug resistant tuberculosis,
- the bacterial activity of delamanid and preliminary data (phase 2 studies) having demonstrated its efficacy in terms of increasing the frequency of conversion to negative bacterial culture results,
- new clinical data (phase 3 study), that has not been able to demonstrate the benefit of the systematic addition of delamanid to an anti-tuberculosis combination regimen with at least 4 effective drugs,
- the fact that delamanid maintains its role in accordance with the marketing authorisation and the updated WHO recommendations.

Recommendations

The Transparency Committee issued its approval for the funding of DELTYBA by the French national health insurance system (hospital use only) as part of a combination regimen for the treatment of patients with multi-drug resistant tuberculosis (MDR-TB), susceptible to delamanid and when the prescription of a group C agent in the WHO classification is indicated.

Methods

The assessment of DELTYBA was founded on evidence-based medicine with a critical analysis of the clinical data. The assessment of the efficacy and safety of DELTYBA is based on new clinical data and WHO updated guidelines.

Written by

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