



Title	Tiotropium in the Treatment of Chronic Obstructive Pulmonary Disease Health Technology Assessment
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Aim

To answer the following research questions:

- What is the efficacy of tiotropium on outcomes relevant for patients with chronic obstructive pulmonary disease (COPD)?
- What is the cost effectiveness of tiotropium in real-world conditions, combining the baseline risk of Belgian patients for specific events and the evidence of treatment effect from randomized controlled trials (RCTs)?

Conclusions and results

Long-acting bronchodilators are recommended in patients who remain symptomatic despite adequate treatment with short-acting bronchodilators. Nevertheless, guidelines do not recommend a specific long-acting bronchodilator. Based on a systematic literature review, tiotropium is not superior to salmeterol in clinically relevant outcomes. Also, tiotropium is more expensive, making the cost-effectiveness balance for this drug unfavorable. Although tiotropium has intrinsic merits, it is currently too expensive from medical and payer perspectives.

Recommendations

- Based on current evidence, a price for tiotropium higher than the price of alternative treatments cannot be supported.
- If the company marketing tiotropium does not agree to a price reduction, reimbursement of this drug should be stopped since a valid and cheaper alternative is available.

Methods

The evidence was summarized on outcomes relevant for patients, including COPD exacerbations, hospital admissions, mortality, quality of life (QoL), and dyspnea. Databases used were INAHTA, CRD (HTA and DARE), NICE, the Cochrane Database of Systematic Reviews, MEDLINE, and EMBASE. In addition to

published studies, attempts were made to identify unpublished studies by searching the FDA and EMEA websites, clinical trial registries, and contacting acknowledged experts. The meta-analysis included 16 RCTs.

The economic evaluation consists of a systematic literature review and a cost-utility analysis combining observational data from a large database (56321 patients) with the results from the clinical efficacy meta-analyses.

Further research/reviews required

- Identify subgroups that could potentially benefit more than the general COPD population from treatment with tiotropium.
- Identify benefits and risks of combining treatments of different long-acting bronchodilators.
- Identify the impact of tiotropium treatment on quality of life (measured by generic instruments) per exacerbation or hospitalization.