European Respiratory Society
Annual Congress 2012

Abstract Number: 2449

Publication Number: P2106

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** Health policy **Keyword 3:** COPD - exacerbations

Title: Cost-effectiveness of adding budesonide/formoterol to tiotropium in severe COPD patients in four Nordic countries

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Body: Objective: To assess the cost-effectiveness of budesonide/formoterol (B/F)+tiotropium (TIO) versus placebo (PBO)+TIO for the treatment of chronic obstructive pulmonary disease (COPD) patients eligible for inhaled corticosteroid/ long-acting β2-agonist from societal and healthcare perspectives in Denmark, Finland, Norway and Sweden. Method: The cost-effectiveness analysis was based on the 12-week, randomised, double-blind CLIMB trial (NCT00496470) of 659 COPD patients with pre-bronchodilator FEV1 ≤50%, and at least one severe exacerbation (hospitalisation, emergency room visit or systemic glucocorticosteroids) the preceding year. Subjects were treated with B/F 320/9µg bid+TIO 18µg qd or PBO bid+TIO 18µg qd. Effectiveness was defined as the number of exacerbations avoided. A sub-analysis included antibiotics in the definition of an exacerbation. Resource use from the trial was combined with 2010 Danish (DKK), Finnish (€), Norwegian (NOK) and Swedish (SEK) unit costs. The incremental cost-effectiveness ratios (ICERs) were estimated by bootstrapping. Results: From a societal perspective, the ICER was estimated at €174 per exacerbation avoided (pEA) in Finland while B/F+TIO was dominant in the other countries. From a healthcare perspective, B/F+TIO was dominant in Norway and the ICERs were estimated at DKK 1,580 (€212), €307, SEK 1,573 (€165) pEA for Denmark, Finland and Sweden, respectively. Including antibiotics decreased ICERs by 8-15%. Sensitivity analyses showed that results were overall robust. Conclusion: The results indicate that B/F+TIO represents a clinical and economic benefit to health systems and society for the treatment of COPD in the Nordic countries.