NHS
Fylde and Wyre
Clinical Commissioning Group

Tiotropium 2.5 micrograms (Spiriva® Respimat®▼)

For use in asthma in adults

Commissioning Statement

NHS Fylde and Wyre Clinical Commissioning Group has agreed to commission the prescribing of tiotropium 2.5 micrograms (Spiriva® Respimat®▼) as an add-on maintenance bronchodilator treatment in adult patients with asthma at step 4 of national and local guidelines for asthma who meet **all** of the following criteria:

- persistent airflow limitation demonstrated by a FEV1 <80% predicted and a ratio of FEV1/FVC <70% and
- currently treated with the maintenance combination of inhaled corticosteroids (≥ 800 micrograms budesonide/day or equivalent*) and long-acting β2 agonists and
- have experienced one or more severe exacerbations in the previous year.

This medicine is classified as GREEN for this indication

- Tiotropium was compared against placebo as add-on therapy to high dose ICS and LABA in two, replicate, 48-week, randomised, phase 3 trials, in asthma patients with persistent airflow limitations, who had experience of at least one severe exacerbation in the last year.
- The changes from baseline in the co-primary endpoints of peak and trough FEV_1 were statistically significantly greater with tiotropium than those achieved with placebo at 24 weeks; however, the improvements over placebo were smaller than those normally considered to be clinically meaningful in asthma patients with baseline airways obstruction (e.g. 12% or 200mL). There were no statistically significant improvements over placebo for secondary endpoints of the number of asthma symptom-free days or the use of rescue medication, and no clinically meaningful improvement in asthma symptom control or patient quality of life as assessed by patients in validated questionnaires.
- Tiotropium significantly increased the co-primary endpoint of time to first severe asthma exacerbation (defined as asthma deterioration needing initiation or doubling of systemic corticosteroids), and also significantly reduced the proportion of patients experiencing a severe exacerbation and the number of severe exacerbations per patient year. In post hoc analysis, 15 patients needed to be treated with tiotropium for a year to avoid one severe exacerbation. Tiotropium did not significantly reduce asthma-related hospitalisations.
- The trials excluded patients with COPD, but all patients enrolled in the trials were required to have $FEV_1 \leq 80\%$ predicted and a ratio of $FEV_1/FVC \leq 70\%$, which would place them in the same category of persistent airflow limitation as patients with COPD. The results may therefore not be generalisable to all patients with uncontrolled asthma who are receiving ICS plus LABA maintenance treatment.
- Trial data to support the use of other add-on treatments at Step 4 of the BTS/SIGN guideline is generally lacking. In addition, higher dose ICS, theophyllines and oral β_2 agonists have well-documented side effects and/or drug interactions.

For details around the evidence, cost effectiveness and for an explanation of the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/

Policy date: March 2015
Review date: March 2018