

Clinical Expert Summary
Tiotropium (Spiriva® Respimat®) 2.5 micrograms solution for inhalation

Tiotropium (Spiriva® Respimat®) as an add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥ 800 micrograms budesonide daily or equivalent) and long-acting beta2-agonists and who experienced one or more severe exacerbations in the previous year.

1. Existing guidelines

Experts referred to the British Thoracic Society and Global Initiative for Asthma guidelines on asthma management, which include a recommendation for tiotropium for asthma. It was additionally highlighted that there were plans to develop guidelines via the Respiratory Health Implementation Group to facilitate the respiratory delivery plan.

2. Disease prevalence/incidence

Clinical experts reported an asthma prevalence of 6.9% and reported that approximately 70% of patients reviewed in asthma clinics are severe or difficult to treat asthmatics.

3. Current treatment options

Current options at the additional add-on therapies stage are increasing the dose of inhaled corticosteroids (ICS), or using theophyllines, leukotriene receptor antagonists and slow release beta2-agonist tablets. Progression to the high-dose therapies stage was additionally highlighted as a treatment option. It was noted by clinical experts that tiotropium is an important option for patients with chronic asthma and, in some cases, aids symptoms in patients who would otherwise be starting expensive biological agents or receiving frequent/continuous oral steroids.

Experts highlighted disadvantages with current treatment options and suggested that it would be advantageous to have tiotropium available as a treatment option to improve symptoms, exacerbation frequency and quality of life of people with difficult to control asthma.

4. Unmet needs

It was highlighted that there were very limited effective treatment options at the additional add-on therapies stage and the high-dose therapies stage, and that patients have high morbidity and healthcare utilisation. Clinical experts raised the difficulties of current treatment options noting that some treatments are ineffective, expensive and associated with adverse side effects. The requirement for future research was highlighted. It was stated that there was a therapeutic gap and that tiotropium would be a sensible treatment option; efficacy was felt to be at least as good as that of alternative treatments and was associated with fewer side effects than high dose inhaled corticosteroids, theophyllines and oral beta2-agonists. One expert expressed the need for better investment in difficult-to-treat asthma services. The unmet need in Wales was highlighted by the Welsh Difficult Asthma Group, who expressed their concern regarding the previous decision by AWMSG not to support the use of tiotropium for people with asthma in Wales.

5. Knowledge of product in given indication

Experts were in agreement that tiotropium was an important treatment option and that it is recommended as an option in national guidelines. Clinicians highlighted that there was an unmet need for treatment options in this patient group, who are particularly difficult to treat. Clinical experts stated that tiotropium would have advantages over current treatment options, which are associated with adverse effects. Clinical experts commented that due to the diagnostic overlap between chronic asthma and chronic

obstructive pulmonary disease, tiotropium has already been used in asthmatic patients. Consequentially, there is ample prescribing experience and prescribers are very familiar with this medication. The availability of tiotropium in other regions of the UK was noted, with clinical experts commenting on the lack of equity in tiotropium not being available in Wales for this indication.

It should be noted that one expert involved in compiling this response declared a personal specific interest and a second expert declared a personal non-specific interest in relation to tiotropium for the indication under consideration.