**South East London Area Prescribing Committee**

**Formulary recommendation**

<table>
<thead>
<tr>
<th>Reference</th>
<th>048</th>
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<tbody>
<tr>
<td><strong>Intervention:</strong></td>
<td>Tiotropium Respimat 2.5 micrograms inhalation solution (Spiriva Respimat®) for the treatment of asthma in adults (Tiotropium is a long acting muscarinic agonist [LAMA])</td>
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<tr>
<td><strong>Date of Decision</strong></td>
<td>February 2016</td>
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<td><strong>Date of Issue:</strong></td>
<td>March 2016</td>
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<td><strong>Recommendation:</strong></td>
<td>Amber – Initiation by respiratory specialist/ can be initiated in primary care on the recommendation of a respiratory specialist</td>
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**Further Information**

- Tiotropium Respimat is accepted for use within South East London as an add-on option for the treatment of adults with asthma at step 4 of the BTS/SIGN treatment algorithm in line with its licensed indication*.
- Tiotropium Respimat will be initiated by a respiratory specialist or initiated in primary care on the advice of a respiratory specialist in line with the SEL guideline for asthma.
- The alternative add-on options at step 4 of the BTS/SIGN algorithm are:
  - An inhaled corticosteroid at a dose of up to 2000 micrograms per day
  - A leukotriene receptor antagonist
  - Theophylline modified release
  - A slow release beta-2 agonist tablet
- Tiotropium has demonstrated statistically significant improvements in FEV1 and reduced exacerbations when compared with placebo at BTS/SIGN step 4 therapy, although the clinical effect was not large.
- There are no comparative data between tiotropium and other add-on options recommended at BTS/SIGN step 4. The alternative add-on treatments recommended at BTS/SIGN step 4 currently do not have a strong evidence base for this particular stage of therapy. The recommendations for these agents are mainly based on extrapolation from trials of add-on therapy to inhaled corticosteroids.
- Educational and supporting resources for managing patients with asthma in primary care will be developed and made available by the SEL Responsible Respiratory Prescribing Group. These will include resources to support healthcare professionals in primary care to step down asthma treatment when appropriate.

* Tiotropium Respimat is licensed for use as an add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 µg budesonide/day or equivalent) and long-acting beta-2 agonists and who experienced one or more severe exacerbations in the previous year.

**Shared Care/Transfer of care required:** Not necessary – inhalers for asthma are already routinely prescribed in primary care without shared care

**Cost Impact for agreed patient group**

- Based on a budget impact model referred to in the evidence evaluation, direct drug costs for adopting at this stage in therapy might approximately be in the region of £15,000 to £25,000 per 100,000 population.
- This equates to between £270,000 to £450,000 for the population of SEL.
- Data on exacerbation rate improvement suggests that addition of tiotropium to a therapeutic regimen may reduce the need for hospital admissions and potentially reduce the need for more expensive subcutaneous therapy (e.g. omalizumab), however the incremental benefit of adding this treatment to the options currently available in this regard is not possible to quantify.

**Usage Monitoring &**

- Trusts to monitor and submit usage and audit data on request to the APC.
<table>
<thead>
<tr>
<th>Impact Assessment</th>
<th>References (from evidence evaluation)</th>
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</table>
| • CCGs to monitor EPACT data.  
• Exception reports from GPs if inappropriate prescribing requests are made to primary care. | 1. Summary of Product Characteristics, Spiriva Respimat. Available [here](http://www.gov.uk/drug-safety-update/tiotropium) [accessed 10.01.2016].  
5. Drug and Therapeutics Bulletin September 2015 p102-104. Tiotropium – what role is asthma?  
23. All Wales Therapeutics and Toxicology Centre 2015. Tiotropium (Spiriva Respimat) 2.5 microgram solution for inhalation.  

**NOTES:**

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS**