

**South East London Area Prescribing Committee  
Formulary recommendation**

<b>Reference</b>	<b>086</b>
<b>Intervention:</b>	Spiolto <sup>®</sup> Respimat <sup>®</sup> (tiotropium/olodaterol) inhalation solution for the treatment of chronic obstructive pulmonary disease (COPD) in adults (Spiolto Respimat is an inhaler containing a combination of the long acting bronchodilators tiotropium [LAMA] and olodaterol [LABA] in a single inhaler device)
<b>Date of Decision:</b>	<b>June 2018</b>
<b>Date of Issue:</b>	<b>June 2018</b>
<b>Recommendation:</b>	<b>GREEN – can be prescribed within agreed criteria for use in primary or secondary care</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• The Spiolto<sup>®</sup> Respimat<sup>®</sup> combination inhaler device is accepted as an option for use in South East London in line with its licence as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).</li> <li>• In line with the local COPD pathway, Spiolto Respimat may be considered as a step up option in patients who experience breathlessness despite initial regular treatment with a long acting muscarinic antagonist (LAMA) and where the addition of a long acting beta agonist (LABA) is appropriate.</li> <li>• Spiolto Respimat is an aerosol spray inhaler device and may be a preferred option for patients without the inspiratory capacity to activate a dry powder inhaler (DPI) device.</li> <li>• Some patients may find the Respimat device more difficult to use than the DPI products because of the priming and administration steps. The device chosen should be based on patient factors, such as inhaler technique.</li> <li>• All patients should be asked to demonstrate their inhaler technique regularly and adherence should be established before stepping up therapy.</li> <li>• The local COPD pathway will be updated to reflect the addition of Spiolto Respimat as a treatment option.</li> </ul>
<b>Shared Care/ Transfer of care required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>• The cost of LAMA/LABA combination inhalers available on the formulary is currently the same, therefore this formulary inclusion is expected to be cost neutral.</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<b>Trusts</b> <ul style="list-style-type: none"> <li>• Monitor and submit usage and audit data on request to the APC.</li> </ul>
	<b>CCGs</b> <ul style="list-style-type: none"> <li>• Monitor EPACT data and audit against the COPD guidelines</li> <li>• Exception reports from GPs if inappropriate prescribing requests are made to primary care.</li> </ul>

Evidence reviewed	References (from evidence evaluation)
	<ol style="list-style-type: none"> <li>1. Global initiative for chronic obstructive lung disease. Guide to COPD diagnosis, management and prevention, a guide for healthcare professionals 2017 edition. Available <a href="#">here</a>. Accessed 23/11/2017</li> <li>2. National Institute of Clinical Excellence (NICE) Clinical Knowledge Summaries (CKS). Chronic Obstructive Pulmonary Disease, September 2015. Available <a href="#">here</a>. Accessed 23/11/2017</li> <li>3. NICE Clinical Guideline [CG101] 2010. Chronic Obstructive Pulmonary Disease in over 16s: diagnosis and management. Available <a href="#">here</a>. Accessed 09/01/2018</li> <li>4. Morjaria J, Rigby A, Maurice A. Inhaled corticosteroid use and the risk of pneumonia and COPD exacerbations in the UPLIFT study. <i>Lung</i> 2017 195 (3) p281-288</li> <li>5. Spiolto Respimat. Summary of Product Characteristics. Available online <a href="#">here</a> (accessed 29/01/2018)</li> <li>6. Buhl R, Maltais F, Abrahams R et al. Tiotropium and olodaterol fixed dose combination versus mono-components in COPD (GOLD 2-4). <i>European respiratory Journal</i> 2015 45 p969-979</li> <li>7. Singh S, Ferguson G, Bolitschek J et al. Tiotropium + olodaterol fixed-dose combination shows clinically meaningful improvements in quality of life versus placebo. <i>European Respiratory Journal</i> 2015 46 Suppl 59 PA2958</li> <li>8. Beeh K, Derom E, Echave-Sustaeta J et al. The lung function profile of once daily tiotropium and olodaterol via Respimat is superior to that of twice daily salmeterol and fluticasone propionate via accuhaler (ENERGITO study). <i>International Journal of COPD</i> 2016 11 p193-205</li> <li>9. Public Assessment Report: Spiolto Respimat 2.5/2.5 microgram (tiotropium and olodaterol). Medicines Evaluation Board (Holland) July 2015.</li> <li>10. Tiotropium delivered via respimat compared with handihaler: no significant difference in mortality in the TIOSPIR trial. Medicines and Healthcare Regulatory Agency Feb 2015</li> <li>11. Spiolto respimat, SMC 1099/15. Scottish Medicines Consortium October 2015</li> </ol>

**NOTES:**

- a) Area Prescribing Committee recommendations and minutes are available publicly via the [APC website](#).
- 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**