The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

**ADVICE:** following a full submission

**олодатерол (Striverdi® Respimat®)** is not recommended for use within NHS Scotland.

**Indication under review:** maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.

In two 48-week studies there was no significant difference between оловатерол 5 microgram and another long acting beta_2_ agonist for the primary endpoints of trough forced expiratory volume in 1 second (FEV_1_) and FEV_1_ area under curve (0 to 3 hours) at week 24.

The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.

The licence holder has indicated their intention to resubmit.

Overleaf is the detailed advice on this product.

**Co-Vice Chairman,**
**Scottish Medicines Consortium**
**Indication**
Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease.

**Dosing Information**
Olodaterol 5 microgram given as two puffs from the Respimat® inhaler once daily, at the same time of the day.

**Product availability date**
9 June 2014

**Summary of evidence on comparative efficacy**

Olodaterol is a once daily long acting beta₂ agonist (LABA), where the dose is delivered by the Respimat® inhaler.¹ It is the second once daily LABA inhaled medicine licensed for the treatment of chronic obstructive pulmonary disease (COPD).

Four randomised, double-blind, placebo-controlled, parallel group studies (1222.11, 1222.12, 1222.13 and 1222.14) have been conducted in patients aged ≥40 years with COPD and who had relatively stable airway obstruction with a post-bronchodilator forced expiratory volume in 1 second (FEV₁) <80% of predicted normal and a post-bronchodilator FEV₁/forced vital capacity (FVC) <70% predicted at the screening visit.¹,² Patients were required to be current or ex-smokers (>10 pack years). Following a two-week run-in period, patients were randomised (stratified by tiotropium use) to 48 weeks treatment with olodaterol (5 micrograms [2 actuations of 2.5 micrograms] once daily, olodaterol 10 micrograms [2 actuations of 5 micrograms]) once daily (both via the Respimat® inhaler), placebo or, in studies 1222.13/14 only, formoterol 12 micrograms twice daily (via the Aerolizer® inhaler). Background therapy with short-acting beta₂-agonists (SABA), inhaled corticosteroids (ICS), oral corticosteroids, long-acting muscarinic antagonists (LAMA), and methylxanthines were permitted in all treatment groups. Efficacy results for the licensed dose only, of olodaterol (5 micrograms daily) are reported in this document.

The co-primary endpoints were change from baseline in trough FEV₁ and FEV₁ area under curve (AUC) (0 to 3 hours) at week 12 (studies 1222.11/12) and week 24 (studies 1222.13/14). Trough FEV₁ was defined as the mean of the FEV₁ obtained at 1 hour prior to daily medication and 10 minutes prior to daily study medication. FEV₁ AUC (0 to 3 hours) was defined as AUC from 0 to 3 hours post-dose using the trapezoid rule, divided by the time duration. Additionally, studies 1222.13/14 included the Mahler transition dyspnoea index (TDI) focal score as a co-primary endpoint. The TDI is a validated instrument that measures the impact of dyspnoea on three domains: functional impairment, magnitude of task and magnitude of effort. Results for the pre-specified analyses of FEV₁ and FEV₁ AUC (0 to 3 hours) are presented in Table 1.
Amended analyses were conducted for the co-primary endpoints in studies 1222.11/12 following database lock and unblinding which involved removal of the treatment-by-tiotropium stratum interaction terms. The treatment effect of olodaterol was of a higher magnitude in these new analyses and all comparisons of olodaterol 5 micrograms versus placebo for the co-primary endpoints were statistically significant.

In a pre-specified pooled analysis of studies 1222.13/14, for the co-primary endpoint of Mahler TDI at 24 weeks, the mean difference from placebo was 0.3 (p=0.17) for olodaterol 5 micrograms and 0.2 (p=0.37) for formoterol. However, in a post-hoc analysis that accounted for patient discontinuations, the difference between olodaterol 5 micrograms and placebo was significant (0.5, p=0.03).\(^1\)

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**Table 1: Pre-specified analysis of primary endpoints (trough FEV\(_1\) and FEV\(_1\) AUC [0 to 3 hours]) for studies 1222.11, 1222.12, 1222.13 and 1222.14**

<table>
<thead>
<tr>
<th>Study</th>
<th>Trough FEV(_1) Change from baseline (SE)</th>
<th>FEV(_1) AUC [0 to 3 hours] Difference; olodaterol versus placebo</th>
<th>Difference; formoterol versus placebo</th>
<th>Change from baseline</th>
<th>Difference; olodaterol versus placebo</th>
<th>Difference; formoterol versus placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study 1222.11; week 12</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olodaterol 5 microgram (n=208)</td>
<td>0.052L (SE 0.016)</td>
<td>0.084L (SE 0.023), p=0.0002</td>
<td>-</td>
<td>0.167L (SE 0.016)</td>
<td>0.164L (SE 0.023), p&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Placebo (n=209)</td>
<td>-0.032L (SE 0.016)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study 1222.12; week 12</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olodaterol 5 microgram (n=209)</td>
<td>0.038L (SE 0.017)</td>
<td>0.033L (SE 0.024), p=0.1624</td>
<td>-</td>
<td>0.155L (SE 0.016)</td>
<td>0.134L (SE 0.022), p&lt;0.0001</td>
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</tr>
<tr>
<td>Placebo (n=216)</td>
<td>0.005L (SE 0.017)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study 1222.13; week 24</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Olodaterol 5 microgram (n=227)</td>
<td>0.021L (SE 0.015)</td>
<td>0.078L (SE 0.021), p=0.0002</td>
<td>-</td>
<td>0.142L (SE 0.015)</td>
<td>0.151L (SE 0.021), p&lt;0.0001</td>
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</tr>
<tr>
<td>Placebo (n=225)</td>
<td>-0.056L (SE 0.015)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Formoterol (n=227)</td>
<td>-0.002L (SE 0.015)</td>
<td>0.054L (SE 0.021), p=0.0088</td>
<td>0.168L (SE 0.015)</td>
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<td></td>
<td>0.177L (SE 0.021), p&lt;0.0001</td>
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<tr>
<td><strong>Study 1222.14; week 24</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olodaterol 5 microgram (n=232)</td>
<td>-0.003L (SE 0.014)</td>
<td>0.053L (SE 0.019), p=0.0055</td>
<td>-</td>
<td>0.116L (SE 0.014)</td>
<td>0.129L (SE 0.019), p&lt;0.0001</td>
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</tr>
<tr>
<td>Placebo (n=235)</td>
<td>-0.055L (SE 0.014)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Formoterol (n=233)</td>
<td>-0.13L (SE 0.014)</td>
<td>0.042L (SE 0.019), p=0.027</td>
<td>0.137L (SE 0.014)</td>
<td></td>
<td></td>
<td>0.150L (SE 0.019), p&lt;0.0001</td>
</tr>
</tbody>
</table>

FEV\(_1\): forced expiratory volume in 1 second, L=litre, SE=standard error, AUC=area under curve.
In studies 1222.13/14 key secondary endpoints were analysed in a hierarchical manner to protect against type 1 error, unlike studies 1222.11/12 where analysis was descriptive only. There were no statistically significant differences between olodaterol 5 microgram versus formoterol at week 24 for FEV$_1$ AUC (0 to 3 hours) (difference -0.026L in study 1222.13 and -0.021L in study 1222.14), and trough FEV$_1$ (difference 0.023L in study 1222.13 and 0.011L in study 1222.14). In all studies the lung function improvements were generally shown in both tiotropium users and non-tiotropium users and the bronchodilator effects of olodaterol were maintained throughout the 48 week treatment period.

Non-spirometric secondary endpoints included exacerbations and use of rescue medication. In all studies there were no statistically significant differences between olodaterol and placebo groups for time to first COPD exacerbation, moderate COPD exacerbation, and first COPD exacerbation leading to hospitalisation. In studies 1222.11 and 1222.14 there was a trend for fewer exacerbations (any and moderate) for olodaterol versus placebo. In studies 1222.11/12 and 1222.13 daily rescue medication use (measured weekly) over the 48 week treatment period was significantly less (and numerically less for study 1222.14) for olodaterol 5 micrograms compared to placebo. St George’s Respiratory Questionnaire (SGRQ) total score after 24 weeks treatment was a secondary endpoint in studies 1222.13/14. In pooled analysis the mean change from baseline in SGRQ total score was -5.6 for olodaterol 5 micrograms, -4.0 for formoterol and -2.8 for placebo; difference versus placebo was -2.8 (p=0.0034) for olodaterol 5 micrograms (but did not reach the minimal clinical important difference of -4.0) and -1.2 (p=0.20) for formoterol.

Additional efficacy data come from six phase III randomised, double-blind, 6-week cross-over studies (1222.24/25, 1222.37/38 and 1222.39/40) conducted in similar patient populations as the studies described previously. All studies included olodaterol 5 microgram, olodaterol 10 microgram and placebo arms and, in addition, studies 1222.24/25 included formoterol 12 micrograms twice daily and studies 1222.39/40 included tiotropium 18 microgram once daily as comparator arms. Concomitant pulmonary medications were permitted except for other LABA in all studies and, in addition, LAMA in studies 1222.39/40 and 1333.37/38. In studies 1222.24/25 and 1222.39/40 olodaterol was significantly superior to placebo for FEV$_1$ AUC (0 to 3 hours) and for mean trough FEV$_1$ response. Improvements in lung function were comparable to twice daily formoterol (studies 1222.24/25) and once daily tiotropium (1222.39/40). Studies 1222.37/38 assessed exercise endurance time (ET) during constant work rate cycle ergometry. Following six weeks treatment the ET for olodaterol 5 microgram was greater than placebo by approximately 1 minute in study 1222.37 and 40 seconds in study 1222.38.

Summary of evidence on comparative safety

Safety data were presented from a pooled analysis of the 48-week studies. Discontinuation from the studies due to adverse events (AE) occurred in 6.2%, 7.8% and 8.4% of patients in the olodaterol 5 microgram, formoterol and placebo groups respectively. Treatment emergent AE occurred in 71%, 69% and 71% of patients in the olodaterol 5 microgram, formoterol and placebo groups respectively. Common treatment emergent AE (≥4%) in the olodaterol 5 microgram, formoterol and placebo groups included; nasopharyngitis (11%, 10%, 7.7%), upper respiratory tract infection (8.2%, 7.0%, 7.5%), bronchitis (4.7%, 2.8%, 3.6%), COPD (26%, 29%, 29%), cough (4.2%, 5.9%, 4.0%) and dyspnoea (4.0%, 5.4%, 4.2%).
On-treatment deaths occurred in 13, 10 and 13 patients in the olodaterol 5 microgram, formoterol and placebo groups respectively. There was an imbalance in deaths due to COPD exacerbation across treatment arms (9, 3 and 4 patients in the olodaterol 5 microgram, formoterol, and placebo groups respectively) although these may not solely be explained by olodaterol exposure. The proportion of on-treatment serious AE (SAE) was balanced across treatment groups; 16%, 15% and 16% in the olodaterol 5 microgram, formoterol and placebo groups respectively. Overall across all treatment groups the most common on-treatment SAE were COPD exacerbation (5.8%) and pneumonia (1.8%) and these occurred in 4.7% and 1.6% of patients on olodaterol 5 microgram (versus 5.9% and 1.5% of patients on formoterol).

Summary of clinical effectiveness issues

Olodaterol is the second, once daily LABA licensed for the treatment of COPD. Indacaterol (Onbrez Breezhaler®) has been accepted for use within NHS Scotland by SMC for the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD. Relevant comparators also include other LABAs, (formoterol and salmeterol, administered twice daily) and also LAMAs (tiotropium, aclidinium and glycopyrronium). The submitting company considered indacaterol to be the only relevant comparator. However, the benefits in practice of once daily versus twice daily LABA and LAMA preparations were not clear and therefore the exclusion of other comparators was not considered to be appropriate.

In the pivotal studies olodaterol was significantly superior to placebo for the primary endpoints of FEV$_1$ AUC (0 to 3 hours) and for trough FEV$_1$ (except for study 1222.12) and the effect was maintained up to week 48. However there were no significant differences between olodaterol and placebo in terms of the secondary endpoint of time to exacerbation (first, moderate or first leading to hospitalisation).

The trough FEV$_1$ response difference from placebo for olodaterol was relatively small compared to study data for other bronchodilators.$^2$ This may be explained by the concomitant pulmonary medications permitted for all patients in the olodaterol studies; tiotropium was taken by 24% of patients; ipratropium, 25%; ICS, 45% and xanthines, 16% in the 48-week studies.$^1$ However National Institute for Health and Care Excellence (NICE) guidance advises using LABA alone for the symptomatic treatment of COPD in patients with stable disease and FEV$_1$ ≥50%, who remain breathless or have exacerbations despite use of SABAs as required.$^3$ Furthermore, a combination inhaler is recommended when ICS are added to LABA, and no ICS alone are licensed for the treatment of COPD. While lung function improvements were shown in the non-tiotropium users strata in the pivotal studies, there are limited data for the use of olodaterol alone, where it is likely be used, in accordance with NICE guidance. NICE guidance does note the use of LAMA in addition to LABA in situations where an ICS is declined or not tolerated; lung function improvements for olodaterol versus placebo were generally shown in the tiotropium users strata from the pivotal studies. Clinical experts consulted by SMC considered that olodaterol would be used in moderate symptomatic COPD in place of a once or twice daily LABA (such as indacaterol, salmeterol or formoterol) or a once daily LAMA (such as tiotropium).

In studies 1222.11/12 alterations were made to the statistical analysis plan following database lock and unblinding. The treatment effect of olodaterol compared to placebo was of lesser magnitude in the pre-specified analysis compared to the amended analysis.

In studies 1222.13/14 there were no statistically significant differences in the co-primary endpoints between olodaterol 5 microgram and formoterol at week 24. Furthermore results of four six-week cross-over studies showed that improvements in lung function for olodaterol were comparable to formoterol and tiotropium. There are no studies comparing olodaterol with indacaterol.
Indirect comparisons were presented by the company for olodaterol vs indacaterol. The key limitation was the lack of indirect comparisons with other relevant comparators in particular; salmeterol (where there are no direct comparative efficacy data) and tiotropium (where comparative efficacy data are limited to 6-week cross over studies). The submitting company argued that comparative efficacy of olodaterol to these comparators was not required, based on indacaterol being compared with some of these alternative treatments in a previous SMC submission – i.e. extension of the comparative chain through the indacaterol review. However, SMC considered this to be a naïve approach and not acceptable. Overall the relevance and credibility of the analyses are considered insufficient.

There are no service implications. Olodaterol would provide clinicians and patients with an alternative to indacaterol and to twice daily LABAs or to LAMAs, as well as a different inhaler device. However as no head-to-head studies have taken place between olodaterol and indacaterol (or other LABA) it is not possible to assess differences in acceptability to the patient of the inhaler devices (Respimat® for olodaterol and the Breezhaler® for indacaterol).

Other data were also assessed but remain commercially confidential.*

**Summary of comparative health economic evidence**

The submitting company presented a cost-minimisation analysis comparing olodaterol with indacaterol as maintenance bronchodilator treatment in patients with COPD. The company has stated that the submission is not selective. However, the analysis appears to have only been undertaken for a sub-group of COPD patients for whom treatment with a LABA is appropriate, as other maintenance treatments have not been considered as relevant comparators by the submitting company (e.g. LAMA or ICS). The time horizon was one year and the perspective was NHS Scotland.

Since no direct comparative data were available to compare olodaterol with indacaterol, the clinical data to support the cost minimisation analysis were drawn from indirect comparisons of varying methodology.

Only medicine costs were included in the analysis, with all other resource use assumed to be equal. The main economic results show that the cost per patient per year is £321 and £356 for olodaterol and indacaterol, respectively. The introduction of olodaterol would therefore be expected to lead to cost savings of £35 per patient per year.

The company presented one way sensitivity analysis varying the estimates of relative risk between the treatment arms for the clinical parameters, in order to help negate any uncertainty surrounding the relative efficacy for these endpoints. In carrying out their analyses for each endpoint, the price of olodaterol was multiplied by the 95% confidence interval relative risk boundaries described within the network meta analysis. The results showed olodaterol to be cost neutral compared with indacaterol when an 11% increase in the cost is assumed. When asked for some further clarification regarding the rationale for the analysis, the company responded that the analyses were designed to demonstrate the robustness of the model to variations in drug value.

The key weaknesses related to the selection of comparators and the evidence base used to support the cost-minimisation analyses:

- Prescribing data show the use of indacaterol to be much lower than the other potential comparators to olodaterol. SMC clinical experts stated salmeterol, tiotropium and formoterol are the predominant treatments currently used in Scotland, and those more likely to be displaced by olodaterol. The exclusion of comparisons to appropriate alternative treatments is
a major weakness of the submission. However, in additional analysis submitted to SMC the company provided cost-minimisation analysis results versus both salmeterol and against a blended comparator of salmeterol, formoterol and indacaterol (weighted according to UK prescribing data). However, there are limitations associated with these additional analyses. As noted above an appropriate indirect comparison, which would be required to underpin the cost-minimisation analysis versus salmeterol, has not been carried out. In addition, any limitations associated with the indirect comparison of olodaterol versus indacaterol mean there are weaknesses associated with the evidence base for the cost-minimisation analysis showing the blended comparator.

- Given the direct comparative data presented showing the relative efficacy of olodaterol versus formoterol, the submitting company was asked to provide further economic analysis comparing olodaterol to formoterol. As the drug acquisition cost of formoterol is lower than olodaterol, treatment with olodaterol would be associated with an annual incremental cost per patient compared with formoterol. Within their response, the company stated that indacaterol is considered to be the only relevant comparator since it is accepted for use in Scotland by SMC, and on the basis that the economic and clinical case was demonstrated for indacaterol versus tiotropium, salmeterol and formoterol (despite the lack of an economic comparison to formoterol). For this reason, the submitting company considered a comparison with indacaterol only to be sufficient to demonstrate the clinical and economic case for olodaterol by assuming the conclusions from the indacaterol SMC advice can be extrapolated to the assessment of olodaterol. As noted above, SMC considered this was a naïve indirect comparison and not acceptable.

Due to these concerns, the economic case has not been demonstrated.

*Other data were also assessed but remain commercially confidential.*

**Summary of patient and public involvement**

A Patient Interest Group Submission was not made.

**Additional information: guidelines and protocols**

The National Institute for Health and Care Excellence (NICE) published an update to clinical guideline 101; Management of chronic obstructive pulmonary disease in adults in primary and secondary care, in June 2010. The guideline includes the following recommendations:

- In people with stable COPD who remain breathless or have exacerbations despite use of SABAs as required, offer the following as maintenance therapy:
  - if FEV₁ ≥ 50% predicted: either LABA or LAMA
  - if FEV₁ < 50% predicted: either LABA with an ICS in a combination inhaler, or LAMA.

- In people with stable COPD and an FEV₁ ≥50% who remain breathless or have exacerbations despite maintenance therapy with a LABA:
  - consider LABA+ICS in a combination inhaler
  - consider LAMA in addition to LABA where ICS is declined or not tolerated.

- Offer LAMA in addition to LABA+ICS to people with COPD who remain breathless or have exacerbations despite taking LABA+ICS, irrespective of their FEV₁.

- Consider LABA+ICS in a combination inhaler in addition to LAMA for people with stable COPD who remain breathless or have exacerbations despite maintenance therapy with LAMA irrespective of their FEV₁.
The following points are also included:

- Choose a drug based on the person’s symptomatic response and preference, the drug’s side effects, potential to reduce exacerbations and cost.
- Do not use oral corticosteroid reversibility tests to identify patients who will benefit from inhaled corticosteroids.
- Be aware of the potential risk of developing side effects (including non-fatal pneumonia) in people with COPD treated with inhaled corticosteroids and be prepared to discuss this with patients.

The Global initiative for chronic Obstructive Lung Disease (GOLD) updated their global strategy for diagnosis management and prevention of chronic obstructive pulmonary disease in January 2014. In terms of pharmacological treatment, four patient groups are identified and treatments for these include;

- **Group A:** In patients with few symptoms and a low risk of exacerbations the use of a short acting bronchodilator when required is recommended as first choice. Alternative choices are a combination of short acting bronchodilators or use of a long acting bronchodilator.
- **Group B:** In patients with more significant symptoms but at a low risk of exacerbations the use of long acting bronchodilators is recommended with no class recommended over another for initial treatment. In patients with severe breathlessness the use of a combination of long acting bronchodilators is an option.
- **Group C:** In patients with few symptoms but a high risk of exacerbations a fixed combination of ICS plus LABA or a LAMA is recommended as first choice. Alternative choices are use of two long acting bronchodilators or ICS plus LAMA.
- **Group D:** In patients with many symptoms and a high risk of exacerbations the first choice is ICS plus LABA or a LAMA. A second choice is ICS plus LABA plus LAMA.

### Additional information: comparators

LABA; indacaterol, salmeterol and formoterol  
LAMA; tiotropium, aclidinium and glycopyrronium

### Cost of relevant comparators

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose Regimen</th>
<th>Cost per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olodaterol</td>
<td>5 micrograms once daily</td>
<td>320</td>
</tr>
<tr>
<td><strong>Long acting beta_2 agonists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indacaterol</td>
<td>150 to 300 micrograms once daily</td>
<td>355</td>
</tr>
<tr>
<td>Salmeterol</td>
<td>50 micrograms twice daily</td>
<td>337</td>
</tr>
<tr>
<td>Formoterol*</td>
<td>12 micrograms twice daily</td>
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<tr>
<td><strong>Long acting muscarinic antagonists</strong></td>
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<td></td>
</tr>
<tr>
<td>Tiotropium (Spiriva Handihaler)</td>
<td>18 micrograms once daily</td>
<td>406</td>
</tr>
<tr>
<td>Tiotropium (Spiriva Respimat)</td>
<td>5 micrograms once daily</td>
<td>406</td>
</tr>
<tr>
<td>Aclidinium</td>
<td>322 micrograms twice daily</td>
<td>347</td>
</tr>
<tr>
<td>Glycopyrronium</td>
<td>44 micrograms once daily</td>
<td>334</td>
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</table>

Doses are for general comparison and do not imply therapeutic equivalence. Costs are from eVadis and MIMS on 1 April 2014. Cost of olodaterol is from the company’s submission.\* There is some dose variation among different formulations of formoterol.
Additional information: budget impact

The submitting company estimated the population eligible for treatment to be 106,650 in year 1 rising to 112,310 in year 5 with an estimated market share of 0.07% in year 1 rising to 0.13% in year 5.

The gross impact on the medicines budget was estimated to be £26k in year 1 and £47k in year 5. As other drugs were assumed to be displaced the net medicines budget impact is expected to be savings of £3k in year 1 and £5k in year 5.
References

The undernoted references were supplied with the submission.

1. Boehringer Ingleheim. Summary of product characteristics for olodaterol (Striverdi® Respimat®).
2. United States Food and Drug Administration briefing package for the Pulmonary-allergy drugs advisory committee meeting. NDA 203108: olodaterol (proposed trade name Striverdi Respimat) for the proposed indication of long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. 29 January 2013.

This assessment is based on data submitted by the applicant company up to and including 16 May 2014.

*Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal: http://www.scottishmedicines.org.uk/About_SMC/Policy_Statements/Policy_Statements

Drug prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.