

**Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)**

Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey (as part of the CRESH system) & associated partner organisations.

**Formulary Extension Briefing Paper**

<b>Medicine details</b>	
<b>Name, brand name</b>	Trimbow NEXThaler dry powder inhaler Beclometasone 88micrograms / formoterol 5micrograms / glycopyrronium 9micrograms each delivered dose
<b>Manufacturer</b>	Chiesi Ltd
<b>Licensed indication</b>	Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist <sup>1</sup>
<b>Formulation</b>	Inhalation powder (extra-fine particles equivalent to 100 micrograms belcometasone pre-dispensed dose)
<b>Usual dosage</b>	Adults: The recommended dose is two inhalations twice daily. (Moderate dose inhaled corticosteroid) Elderly No dose adjustment is required in elderly patients (65 years of age and older).

<b>Disease and potential patient group</b>	
<b>Brief description of disease</b>	COPD is chronic respiratory condition characterised by airflow limitation that is not fully reversible and is associated with an abnormal inflammatory response in the lungs to noxious particles or gases (e.g., cigarette smoking). It is a heterogeneous disease in terms of chronic respiratory symptoms (e.g., dyspnoea on exertion and cough), acute exacerbations, severity and rate of progression.
<b>Potential patient numbers per 100,000</b>	NICE 4.5% of all people over 40 live with a diagnosis of COPD Prevalence of COPD in Surrey Heartlands (QoF registers 2021/22) is 1,269 per 100,000 (1.26%) NICE COPD guideline NG115 <sup>2</sup> estimates 16% of patients with COPD should be on triple therapy with LAMA + LABA + ICS. This would be about 2,284 patients in Surrey Heartlands. EPACT2 prescribing suggests ~9,300 patients prescribed triple therapy for respiratory disease in Surrey Heartlands.

## SUMMARY

### Reason for formulary extension

Trimbow NEXThaler® is a dry-powder inhaler device containing three active pharmacological components - an inhaled corticosteroid (ICS) with a long acting beta agonist (LABA) and a long acting antimuscarinic antagonist (LAMA), as a combined triple therapy for patients with COPD.

Trimbow metered-dose inhaler (5/87/9) is already available within Surrey Heartlands for the management of COPD (equivalent dose to Trimbow NEXThaler. The NEXThaler device is approved for use within Surrey Heartlands, presented as an ICS/LABA combination called Fostair indicated for asthma and COPD. Advantages of the NEXThaler device include requiring low level of manual dexterity to use, includes a dose counter with a warning when 10 doses remaining, and gives relatively consistent dosing across a range of inspiratory flow rates.

Triple inhaler therapy is recommended in both [local<sup>3</sup>](#) and national COPD guidelines ([NICE NG115<sup>2</sup>](#)) in some patients with COPD. These devices are cost effective compared to the separate devices when used in appropriate patients. They may also aid compliance in some patients decreasing from one inhaler to two. They do however decrease flexibility in dosing so appropriate patients should be established on an effective dose of triple therapy before the triple therapy inhalers are initiated. NICE NG115 recommends that clinicians should minimise the number of inhalers and the number of different types of inhaler used by each person as far as possible.

Research suggests that around 87% of people with COPD or asthma make errors when using a pMDI, and 46% of these errors reduce drug effectiveness<sup>6</sup>. NICE NG115 recommends that an alternative inhaler should be provided if a person cannot use a particular one correctly or it is not suitable for them. Current triple therapy inhaler devices available in Surrey Heartlands for COPD are Trimbow pMDI, and Trelegy Ellipta (dry p powder inhaler). An additional dry powde inhaler device would widen the alternative inhalers available for this patient group.

The [Delivering a Net Zero NHS<sup>5</sup>](#) requires the NHS to achieve an 80% reduction in it's carbon footprint by 2040. Inhalers account for approximately 3% of the NHS carbon footprint (most inhaler prescribing is in primary care). The propellant used in metered dose inhalers (MDI) is responsible for most of these emissions. Alternative options with a significantly lower carbon footprint exist, such as dry power inhalers (DPI). The UK has a high prescribing date of MDIs compared with other European countries. These countries have demonstrated that safe and effective care can still be delivered using other inhaler devices.

Local respiratory health care professionals have requested Trimbow NEXThaler as a alternative triple therapy inhaler for patients with COPD.

### Tick one box

**Addition to formulary**                      **Yes**

Replacement of originator product/s

Name of product/s.....

### Evidence as necessary

Triple therapy combination inhalers are recommended as a treatment option in COPD, where clinically appropriate, in line with NICE guidance<sup>2</sup> (NG115 –updated July 2019) as follows:  
Before starting LAMA+LABA+ICS, conduct a clinical review to ensure that:

- the person's non-pharmacological COPD management is optimised, and they have used or been offered treatment for tobacco dependence if they smoke
- acute episodes of worsening symptoms are caused by COPD exacerbations and not by another physical or mental health condition.

- the person's day-to-day symptoms that are adversely impacting their quality of life are caused by COPD and not by another physical or mental health condition.

For people with COPD who are taking LABA+ICS, offer LAMA+LABA+ICS if:

- their day-to-day symptoms continue to adversely impact their quality of life or
- they have a severe exacerbation (requiring hospitalisation) or
- they have 2 moderate exacerbations within a year.

For people with COPD who are taking LAMA+LABA, consider LAMA+LABA+ICS if:









- they have a severe exacerbation (requiring hospitalisation) OR
- they have 2 moderate exacerbations within a year

For people with COPD who are taking LAMA+LABA and whose day-to-day symptoms adversely impact their quality of life:

- consider a trial of LAMA+LABA+ICS, lasting for 3 months only
- after 3 months, conduct a clinical review to establish whether or not LAMA+LABA+ICS has improved their symptoms:
  - if symptoms have not improved, stop LAMA+LABA+ICS and switch back to LAMA+LABA and consider referral to a specialist respiratory team
  - if symptoms have improved, continue with LAMA+LABA+ICS.

### Greener NHS programme:

Trimbow NEXThaler offers a formulary choice which has a lower inhaler carbon footprint than many other options (note not all inhalers listed below are available in Surrey Heartlands).

Inhaler brand name	Inhaler image	Carbon footprint	Active ingredient(s)	Type of inhaler
Trelegy® Ellipta® 92/55/22 micrograms DPI			Fluticasone furoate & vilanterol & umeclidinium	ICS + LABA + LAMA
Trimbow® 87/5/9 micrograms pMDI			Beclometasone & formoterol & glycopyrronium	ICS + LABA + LAMA
Trimbow® NEXThaler® 88/5/9 micrograms DPI			Beclometasone & formoterol & glycopyrronium	ICS + LABA + LAMA
Trixeo® Aerosphere® 5/7.2/160 micrograms pMDI			Budesonide & formoterol & glycopyrronium	ICS + LABA + LAMA

Ref: <https://www.prescqipp.info/our-resources/bulletins/bulletin-295-inhalercarbon-footprint/>

### Cost implications

There is no cost differential to other triple therapies currently approved in Surrey Heartlands so this should not affect the current cost implications

Cost of product: £44.50 /120 dose inhaler

Annual cost per patient: £534 p.a.

**Availability of PAS and details (if appropriate): NA**

**Availability of homecare service (if appropriate): NA**

**Alternative treatments and cost per (patient per year / per month as appropriate)**

	<b>Cost per month</b>	<b>£ / year</b>	<b>TLS status</b>
Trimbow pMDI (87/5/9)	£44.40 (based on 4 puffs/day)	£534	Green
Trimbow NEXThaler	£44.40 (based on 4 puffs/day)	£534	TBC
Trelegy Ellipta DPI	£44.40 (based on 1 puffs/day)	£534	Green

**Impact to patients**

As with all inhaler devices, patients will require training in how to use NEXThaler. NEXThaler provides an alternative device choice for patients suitable for a DPI. If coordination/ manual dexterity is poor, or patient has insufficient inspiratory flow to activate a DPI, a pMDI plus a spacer may be required.

Provides options for patients to choose low carbon device.

Fixed-dose triple therapy inhaled combination therapy in one inhaler may help improve health status compared to treatment using multiple inhalers. This may improve compliance in this group of patients.

**Impact to primary care**

The NEXThaler device is familiar to health care professionals in primary care, as it is widely prescribed as Fostair for asthma.

It offers patients a wider choice of devices for COPD management. It also supports the NHS to Delivery a Net Zero NHS by offering a low carbon inhaler.

Patients currently on triple therapy should be reviewed and if inhaled corticosteroids are not indicated stepped down as per local guidelines.

**Impact to secondary care**

Secondary care clinicians have requested Trimbow NEXThaler for COPD management. Similarly, to primary care they are familiar with this device and it supports moving to low carbon inhalers.

More severe patients who are in hospital following an exacerbation may be indicated for initiation of triple therapy therefore this may be a useful addition to the portfolio.

**Impact to CCGs**

Minimal impact on prescribing cost – all triple therapy inhalers for COPD have the same cost per patient. Improved patient care through wider choice of inhaler and supports sustainability agenda by offering an inhaler with a low carbon footprint.

**Implementation**

COPD guidelines will be amended to include Trimbow NEXThaler as an option for triple therapy in COPD.

Health care professionals may consider a change in inhaler device from a pMDI following review and assessment of inhaler technique in suitable patients.

**Recommendation to APC**

**PbRe:** Not applicable



Colour classification guidelines

**Recommended traffic light status (see attached guidelines):**  
Green for COPD

**Additional comments:**

**References:**

1. [Trimbow NEXThaler SPC](#). Accessed 13 April 2023
2. NICE. Chronic obstructive pulmonary disease in over 16s: diagnosis and management NG115. Jul 2019. <https://www.nice.org.uk/guidance/ng115>. Accessed 13 April 2023.
3. Surrey Heartlands Area Prescribing Committee. [COPD Primary Care Management Guidelines. February 2020](#). Accessed 13 April 2023.
4. Spencer S et al. Interventions to improve inhaler technique for adults with chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2021, Issue 7 Art. No: CD014956. [DOI: 10.1002/14651858.CD014956](https://doi.org/10.1002/14651858.CD014956). Accessed 11 April 2023.
5. NHS England. [Delivering a 'Net Zero' National Health Service](#). July 2022. Accessed 13 April 2023.

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Declaration of Interest:

None

Date: 12/7/2022

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Declaration of Interest:

None

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**VERSION CONTROL SHEET**

Version	Date	Author	Status	Comment
v.1.1	13/04/23	Celia Houlihan / Helen Marlow		Draft for consultation
v.1.2	23/05/23	Celia Houlihan / Helen Marlow		Final for APC