

North Staffordshire and Stoke-on-Trent Area Prescribing Committee

Medicine Review Summary

Trelegy® Ellipta (Fluticasone 92mcg/Umeclidinium 55mcg/ Vilanterol 22mcg /dose) powder inhaler

Verdict:	
Formulary inclusion:	Trelegy® is to be included in the North Staffs Joint Formulary
Formulary category:	Green
Restrictions:	To be used in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease (accessed via www.goldcopd.org) and the locally approved 'At a Glance Guide:Stable COPD'.
Reason for inclusion:	The New Medicines Committee was satisfied with the evidence to support the safety and efficacy of Trelegy® and acknowledged the fact that the individual components were already well established in clinical practice. The improvement in patient compliance associated with a single inhaler and cost saving when compared to the individual components were noted. The New Medicines Committee acknowledged that locally approved guidelines reflect the GOLD guidelines for management of COPD whereas the licensed indication for Trelegy® places its use after ICS and LABA. The Area Prescribing Committee considered this and supported the use of Trelegy® in line with GOLD and local guidelines; prescribers need to be aware of this.
Link to formulary:	Stoke-on-Trent CCG website: https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/joint-formulary North Staffordshire CCG website: https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/joint-formulary Secondary care: Trust Intranet→ Clinicians→ Support services → Pharmacy →North Staffordshire Joint Formulary
Link to medicine review summary:	Stoke-on-Trent CCG website: https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets North Staffordshire CCG website: https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets Secondary care: Trust Intranet→ Clinicians→ Support services → Pharmacy → Joint Formulary Related Documentation → North Staffordshire & Stoke-on-Trent Area Prescribing Committee Medicine Review Summary Verdict Sheets
Link to full review:	Stoke-on-Trent CCG website: https://www.stokeccg.nhs.uk/stoke-governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets North Staffordshire CCG website: https://www.northstaffscg.nhs.uk/governance/policies/medicines-optimisation/formulary-review-and-verdict-sheets Secondary care: Trust Intranet→ Clinicians → Support Services → Pharmacy → Joint Formulary Related Documentation → New Medicine Committee (NMC) Medicines Reviews

Review summary:**Formulary Application:**

Trelegy® Ellipta powder inhaler was reviewed for inclusion in the North Staffordshire Joint Formulary for 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 β 2-agonist. Dr Imran Hussain (Respiratory Consultant) attended the meeting on 10th January 2017 to support the application.

Licensed indications¹: 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 β 2-agonist

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Related Guidance:

NICE²: www.nice.org.uk

Global Initiative for Chronic Obstructive Lung Disease (GOLD)³: www.goldcopd.org.

Efficacy and safety:

Safety and efficacy of the three individual components is already established in currently used licensed products (Relvar® Ellipta (fluticasone and vilanterol) and Incrus® Ellipta (umeclidinium))

In the FULFIL⁴ trial, Trelegy® once a day was compared with Symbicort® (budesonide/formoterol) twice a day to determine the effects of Trelegy® on lung function and health-related quality of life. Trelegy® demonstrated significant clinical improvement with a mean change from baseline FEV₁ at week 24 of 142ml (95% CI, 126 to 158) for Trelegy® and -29 ml (95% CI, -46 to -13) for Symbicort® (p<0.001).

There was a statistically significant reduction in moderate/severe exacerbation rate with triple therapy Trelegy® compared to dual Symbicort® therapy (35% reduction; 95% CI, 14-51; P = 0.002) over the 24 week treatment period in the ITT population. Fewer patients were hospitalised for exacerbations in the triple therapy group (n=12) compared to the double therapy group (n=22).

These results support the benefits of single-inhaler triple therapy compared with dual therapy in patients with advanced COPD. This still does not reflect the recommendation by GOLD guideline of stepping up from LABA+LAMA to triple therapy. There is no comparison with LABA+LAMA. The combination therapy is still a better option than the use of two different inhalers in relation to compliance and good inhaler technique.

The safety profile of Trelegy® therapy and Symbicort® therapy reflected the known profiles of the components. The most common adverse events were nasopharyngitis (7% and 5% for Trelegy® and Symbicort® respectively) and headache (5% and 6% for Trelegy® and Symbicort® respectively).

Costs:

LabelDescription	Tradename	Pack size (doses)	Price exc VAT	UHM Price inc VAT	Price comparison incl VAT	Price difference incl VAT
TRIMBOW 87microgram/ 5microgram/9microgram INHALER (120)	TRIMBOW	120				
FOSTAIR 200/6 INHALER (120-dose)	FOSTAIR	120				
FOSTAIR 100/6 INHALER (120-dose)	FOSTAIR	120				
GLYCOPYRRONIUM 44microgram BREEZHALER & 30 CAPSULES	SEEBRI BREEZHALER	30				
TRELEGY 92/55/22 INHALER	TRELEGY ELLIPTA	30				
RELVAR ELLIPTA 92/22 INHALER (30-dose)	RELVAR ELLIPTA	30				
RELVAR ELLIPTA 184/22 INHALER (30-dose)	RELVAR ELLIPTA	30				
UMECLIDINIUM 55microgram INHALER (30 dose)	INCRUSE ELLIPTA	30				

References:

¹ Summary of Product Characteristics Trelegy® Ellipta 92 micrograms/55 micrograms/22 micrograms inhalation Last Updated on eMC 23rd-Nov-2017 <https://www.medicines.org.uk/emc/product/8666> (Accessed online 12th Jan 2018)

² NICE Clinical guideline CG101: Chronic obstructive pulmonary disease in over 16s: diagnosis and management. June 2010. Accessed via www.nice.org.uk (Accessed online 12th January 2018)

³ Global Initiative for Chronic Obstructive Lung Disease global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease 2017 report. Accessed via www.goldcopd.org (Accessed online 9th January 2018)

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⁴ Lipson DA, Barnacle H, Birk R, et al. FULFIL Trial: Once-Daily Triple Therapy for Patients with Chronic Obstructive Pulmonary Disease. American journal of respiratory and critical care medicine. 2017;196(4):438-446