

South East London Area Prescribing Committee Formulary recommendation

Reference	084
Intervention:	<p>Triple combination therapy inhalers for adults with chronic obstructive pulmonary disease (COPD):</p> <p>Trelegy[®] Ellipta[®] (fluticasone furoate/umeclidinium bromide/vilanterol) and Trimbow[®] (beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium)</p> <p>(These inhalers each deliver a combination of a corticosteroid and two long acting bronchodilators in a single inhaler device)</p>
Date of Decision:	June 2018
Date of Issue:	June 2018
Recommendation:	Amber 1 - can be initiated in primary care on the recommendation of a respiratory specialist
Further Information	<ul style="list-style-type: none"> • Trelegy[®] Ellipta[®] and Trimbow[®] are accepted for use within South East London as an option for the treatment of adults with moderate to severe chronic obstructive pulmonary disease (COPD). • In line with the local COPD pathway, Trelegy and Trimbow may be considered in patients who continue to have an FEV1 <50% predicted and ≥2 exacerbations per year, despite dual bronchodilation therapy (with a long acting beta-agonist [LABA] and a long acting antimuscarinic [LAMA]). • These inhalers may also be considered for use in patients appropriately receiving triple therapy (inhaled corticosteroid [ICS]/LABA and LAMA) in separate devices. It should be noted that switching of patients who are stable on other triple therapy regimens to Trelegy or Trimbow may not be appropriate. • Trelegy and Trimbow are licensed as maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of ICS and LABA. • Therefore the indication for use approved in SEL is off label, however escalating to triple therapy from ICS/LABA (as per licensing) would not be conventional practice; because a patient would normally be trialled on LABA/LAMA first, then ICS introduced last line as per Global initiative for chronic obstructive lung disease (GOLD) recommendations. • Trelegy is a dry powder inhaler device and Trimbow is a metered dose inhaler device. The device chosen should be based on patient factors, such as inhaler technique. • All patients should be asked to demonstrate their inhaler technique regularly and adherence should be established before stepping up therapy. • Treatment with either of these inhalers should only be started on the recommendation of a respiratory specialist. • The local COPD pathway will be updated to reflect the addition of these inhalers to the treatment options.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • The introduction of these triple therapy inhalers is expected to result in cost savings. • Extrapolating existing prevalence data suggests that there could be 4,500 patients with COPD eligible for treatment with these inhalers in SEL. • If the average cost saved as a result of switching to either of these inhalers (depending on the original combination of inhalers) is £12 per month, per patient; the overall potential savings for SEL per month will be in the region of £54,000. • This represents a maximum figure according to current prevalence.

Usage Monitoring & Impact Assessment	Trusts <ul style="list-style-type: none"> Monitor and submit usage and audit data on request to the APC. CCGs <ul style="list-style-type: none"> Monitor EPACT data Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	References (from evidence evaluation) Trelegy Ellipta review: <ol style="list-style-type: none"> Global initiative for chronic obstructive lung disease. Guide to COPD diagnosis, management and prevention, a guide for healthcare professionals 2017 edition. Available here. Accessed 23/11/2017. National Institute of Clinical Excellence (NICE) Clinical Knowledge Summaries (CKS). Chronic Obstructive Pulmonary Disease, September 2015. Available here. Accessed 23/11/2017 National Institute of Clinical Excellence (NICE) Clinical Guideline [CG101] 2010. Chronic Obstructive Pulmonary Disease in over 16s: diagnosis and management. Available here Accessed 09/01/2018 European Medicines Agency Public Assessment Report (EPAR), last updated Jan 2018. Available here. Accessed 23/11/2017. NICE Technology Appraisal Guidance. NICE TA461: Roflumilast for treating chronic obstructive pulmonary disease. Published July 2017. Available here. Accessed 23/01/2018 Siler et al. Efficacy and safety of umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: Results of two randomized studies. Respiratory Medicine 2015; 109: 1155-63. Lipson 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: 438-46. Jones PW et al. Minimal clinically important differences in pharmacological trials. Am J Respir Crit Care Med 2014; 189: 250-5 Montuschi P et al. Triple inhaled therapy for chronic obstructive pulmonary disease. Drug Discov Today 2016; 21: 1820-7. Electronic Medicines Compendium. Trelegy Ellipta 92 micrograms/55 micrograms/22 micrograms inhalation powder. Last updated November 2017. Via www.medicines.org. Accessed 07/02/2018. Trimbow review: <ol style="list-style-type: none"> Global initiative for chronic obstructive lung disease. Guide to COPD diagnosis, management and prevention, a guide for healthcare professionals 2017 edition. Available here. Accessed 23/11/2017. National Institute of Clinical Excellence (NICE) Clinical Knowledge Summaries (CKS). Chronic Obstructive Pulmonary Disease, September 2015. Available here. Accessed 23/11/2017 National Institute of Clinical Excellence (NICE) Clinical Guideline [CG101] 2010. Chronic Obstructive Pulmonary Disease in over 16s: diagnosis and management. Available here Accessed 09/01/2018 European Medicines Agency Public Assessment Report (EPAR), last updated Aug 2017. Available here. Accessed 23/11/2017. NICE Technology Appraisal Guidance. NICE TA461: Roflumilast for treating chronic obstructive pulmonary disease. Published July 2017. Available here. Accessed 23/01/2018 Singh et al. Single inhaler triple therapy versus inhaled corticosteroid plus long-acting β2-agonist therapy for chronic obstructive pulmonary disease (TRILOGY): a double-blind, parallel group, randomised controlled trial. Lancet 2016; 388: 963-73. Vestbo et al. Single inhaler extrafine triple therapy versus long-acting muscarinic antagonist therapy for chronic obstructive pulmonary disease (TRINITY): a double-blind, parallel group, randomised controlled trial. Lancet 2017; 389: 1919-29. Jones PW et al. Minimal clinically important differences in pharmacological trials. Am J Respir Crit Care Med 2014; 189: 250-5. Montuschi P et al. Triple inhaled therapy for chronic obstructive pulmonary disease. Drug Discov Today 2016; 21: 1820-7. Electronic Medicines Compendium. Trimbow 87 micrograms/5 micrograms/9 micrograms pressurised inhalation, solution. Last updated 26 Jul 2017. Via www.medicines.org.uk. Accessed 23/11/2017

NOTES:

- Area Prescribing Committee recommendations and minutes are available publicly via the [APC website](#).
- 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.
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South East London Area Prescribing Committee. A partnership between NHS organisations in South East London:

Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark Clinical Commissioning Groups (CCGs) and GSTFT/KCH /SLAM/ & Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust