AREA PRESCRIBING COMMITTEE – Birmingham, Sandwell, Solihull and environs

Decision Making Support Tool

The following document supports the committee to consider formulary applications against defined criteria.

Formulary application reference:	APCBSSE/0008
Drug name and formulations:	Vilanterol / fluticasone (Relvar Ellipta®) Fixed dose LABA/ICS combination

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Vilanterol is relatively new product with limited experience. Concerns that the name Relvar looks similar to "reliever" and may therefore be used on an "as needed " basis, rather than regularly. Its safety profile in patients with COPD is similar to that in patients with asthma, except for a higher incidence of fracture and pneumonia in patients with COPD. Adrenal suppression is a potential risk although data on the effects of Relvar Ellipta® on cortisol excretion are inconsistent.
Clinical effectiveness	*Established licensed product*	Equivalent to other LABA/ICS agents. Once daily dosage.
Strength of evidence		Considered to be relatively weak. No comparative data for exacerbation rate or other patient-oriented outcomes against placebo or other LABA/ICS inhalers.
Cost effectiveness or resource impact	*£*	Cost-effective device- £338 pa.
Place of therapy relative to available treatments	*1/2nd tier*	For patients with FEV_1 < 50% predicted who remain breathless or have exacerbations despite using short-acting bronchodilators as needed; **OR** as a treatment option in patients with FEV_1 ≥ 50% predicted with persistent exacerbations or breathlessness despite maintenance therapy with a LABA; **OR** in combination with a LAMA (triple therapy) in patients who remain breathless or have exacerbations despite taking LABA/ICS, irrespective of FEV_1.

National guidance and priorities	*NICE, MTRAC*	NICE guideline on management of COPD (2010). MTRAC verdict- lower place, weaker evidence. SMC accepted for restricted use April 2014.
Local health priorities	*CCG views*	Cost-effective treatment of COPD is a priority in Primary Care.
Equity of access	*Equality assessment*	No restrictions.
Stakeholder views	*Define wider groups to be engaged*	Respiratory Network views considered (HEFT/City & Sandwell/ UHB)
Implementation requirements	*Requires, RICAD ESCA etc.*	Draft COPD guideline available.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	Given that the LAMA containing agents have been rejected, commonality of device rationale is no longer relevant. There seemed to be no compelling evidence to add another LABA/ICS combination, and it was accepted that the potential saving offered by this combination was significantly reduced with the availability of generic versions of fluticasone/salmeterol combination inhaler.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	