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/0010
Drug name and formulations:	Umeclidinium/ vilanterol (Anoro Ellipta®) Fixed dose LAMA/LABA combination

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Vilanterol is relatively new agent with limited experience. Black triangle drug.
Clinical effectiveness	*Established licensed product*	There are some reservations about the evidence base for LAMA component umeclidinium: the efficacy data for use of umeclidinium alone was limited as ICS were also permitted in many of the studies. No evidence of direct comparisons. Once daily dosage.
Strength of evidence		Limited comparative studies
Cost effectiveness or resource impact	*£*	Cost- effective device £395 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 PRN, and have declined or cannot tolerate ICS; OR for patients with FEV_1 ≥ 50% predicted with persistent exacerbations or breathlessness despite a long acting bronchodilator and have declined or cannot tolerate ICS.
National guidance and priorities	*NICE, MTRAC*	NICE guideline on management of COPD (2010), The 2015 GOLD report on COPD. SMC accepted Feb 2015.
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*	Draft COPD guideline available

	etc.	

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	The comparator studies are more limited than with Ultibro Breezhaler®. Vilanterol is a relatively new product with limited experience in this country. There are some reservations about the evidence base for LAMA component umeclidinium. Multiple combination inhalers may cause confusion and allow less familiarity with the various devices. For simplification, the members agreed to limit the LAMA/LABA options to 2 devices.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	