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/0013
Drug name and formulations:	Umeclidinium (Incruse Ellipta®)

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	There is no data to show that it is a safer product than other LAMA options. Black triangle drug. Easy to use device.
Clinical effectiveness	*Established licensed product*	The committee were unable to identify any significant differences over other LAMA products (tiotropium, aclidinium or glycopyrronium). Once daily dosage.
Strength of evidence		Considered to be relatively weak. There are quality issues with umeclidinium studies. The efficacy data for use of umeclidinium alone was limited as ICS were also permitted in many of the studies. No QOL data.
Cost effectiveness or resource impact	*£*	The annual costs of umeclidinium 55 microgram daily are £335 (compared to aclidinium £348, tiotropium £408, glycopyrronium £335 annually).
Place of therapy relative to available treatments	*1/2nd tier*	4th LAMA to be marketed in UK for maintenance treatment of COPD
National guidance and priorities	*NICE, MTRAC*	NICE guideline on management of COPD (2010). SMC accepted Dec 14.
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:	There are quality issues with umeclidinium studies. Given that the LAMA/LABA containing agent has been rejected, commonality of device rationale is no longer relevant.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	