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/0009
Drug name and formulations:	Glycopyrronium/ Indacaterol (Ultibro Breezhaler®) Fixed dose LAMA/LABA combination

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	No patient safety issues identified. Black triangle drug.
Clinical effectiveness	*Established licensed product*	Established licensed product. Glycopyrronium is already on the formulary, so clinicians will be familiar with it, and the device. It is once daily dosage.
Strength of evidence		There is evidence of small statistically significant improvement in health status and dyspnoea for Ultibro compared to tiotropium and Seretide.
Cost effectiveness or resource impact	*£*	Highest acquisition cost of LABA/LAMA devices: £449 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 Dec 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:	
Formulary status (RAG) and rationale	GREEN: This product is less cost effective than other 2 LAMA/LABA options; however it does allow easier step up for patients managed on glycopyrronium monotherapy with the same device. Glycopyrronium is already on the formulary, so clinicians will be familiar with it, and the device. It is once daily dosage.
Implementation requirements:	COPD Guideline
Implementation monitoring:	