

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/0012
Drug name and formulations:	Aclidinium/formoterol inhaler (Duaklir Genuair®) Fixed dose LAMA/LABA combination.

Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	No patient safety issues identified. Black triangle drug.
Clinical effectiveness	<i>Established licensed product</i>	Established licensed product. There is clinical experience with the separate components. Comparable efficacy to other LAMA/LABA combinations. Twice daily dosage.
Strength of evidence		Evidence of efficacy against placebo in controlled clinical trials. Improvement in quality of life against baseline.
Cost effectiveness or resource impact	£	Cost- effective device £395 pa
Place of therapy relative to available treatments	<i>1/2nd tier</i>	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	<i>NICE, MTRAC</i>	NICE guideline on management of COPD (2010), The 2015 GOLD report on COPD. SMC accepted March 2015.
Local health priorities	<i>CCG views</i>	Cost-effective treatment of COPD is a priority in Primary Care.
Equity of access	<i>Equality assessment</i>	No restrictions.
Stakeholder views	<i>Define wider groups to be engaged</i>	Respiratory Network views considered (HEFT/City & Sandwell/ UHB)
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	Draft COPD guideline available

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Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	<p>GREEN: The Genuair® range was favoured as there is a range of classes of agents and the committee were advised that pipeline agents were expected (LABA and LABA/ICS)</p> <p>There is experience with the separate drugs over a longer period than the other new combinations. The device is easy to use.</p> <p>This product is one of the two more cost effective products.</p> <p>Acclidinium is already on formulary, so there is familiarity with the LAMA component and the device. This combination was strongly supported by respiratory consultants in terms of comparable efficacy.</p>
Implementation requirements:	COPD Guideline
Implementation monitoring:	