

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/0067	
Drug name and formulations:	Sialanar® (glycopyrronium bromide) oral solution 400mcg/ml	
Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	Significant side effect profile outlined within the application. Respiratory side effects (thickening of oral secretions) acknowledged during presentation. Anticholinergic side effects considered to be minimal at doses used. However, as a licensed product with known bioavailability profile, Sialanar® will be safer than unlicensed specials. Licensed for use with PEG, nasogastric and G tubes.
Clinical effectiveness	<i>Established licensed product</i>	Established therapy for sialorrhoea.
Strength of evidence		Strong, RCTs vs placebo.
Cost effectiveness or resource impact	£	Expensive but more cost-effective than current unlicensed products.
Place of therapy relative to available treatments	<i>1/2nd tier</i>	Second line to hyoscine patches.
National guidance and priorities	<i>NICE, MTRAC</i>	NICE evidence summary (ES5, Feb 2017). NICE guideline NG62 (Jan 2017)- Cerebral palsy in under 25s: assessment and management , includes glycopyrronium bromide (oral or by enteral tube) as an option for anticholinergic medication to reduce severity of drooling.
Local health priorities	<i>CCG views</i>	This treatment is for a well-known condition in small cohort of very poorly patients.
Equity of access	<i>Equality assessment</i>	N/A
Stakeholder views	<i>Define wider groups to be engaged</i>	N/A
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	None, RICaD not deemed necessary.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	Approved as Amber. Specialist initiation and stabilisation.
Implementation requirements:	
Implementation monitoring:	