

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/0058	
Drug name and formulations:	Gardasil® Quadrivalent Human Papillomavirus vaccine for Recurrent Respiratory Papillomatosis (RRP)	
Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	No issues regarding safety; already being used in teenage girls in national immunisation campaign for prevention of cervical cancer. However safety of Gardasil® in children below 9 years of age has not been established.
Clinical effectiveness	<i>Established licensed product</i>	Licensed product but off-label use for this indication. Efficacy of Gardasil® in children below 9 years of age has not been established. Clinical effectiveness based on biological plausibility.
Strength of evidence		Relatively weak; 2 case studies involving small numbers of patients.
Cost effectiveness or resource impact	£	Opportunity cost of £260 per course, however resource impact is unknown due to variability in interval between surgical interventions.
Place of therapy relative to available treatments	<i>1/2nd tier</i>	Adjuvant therapy to surgical resection of laryngeal lesions.
National guidance and priorities	<i>NICE, MTRAC</i>	None
Local health priorities	<i>CCG views</i>	Primary Care not supportive; covered by Collaborative Commissioning Policy on Experimental and Unproven Treatments.
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>	Depends on final RAG status.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	RED – for ENT specialists only for recurrent respiratory papillomatosis (RRP)
Implementation requirements:	
Implementation monitoring:	APC members would welcome audit data from Trusts using it to support reduction in intervals between surgical interventions.