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/0064
Drug name and formulations:	Ethinylestradiol tablets: 2 mcg (Specials) and 10 mcg (licensed)

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	No safety issues relating to the drug; millions of women worldwide use ethinylestradiol in the form of the combined oral contraceptive pill, which has a good safety profile. Adverse drug reactions and drug interactions will be minimal at this dose and for this indication. The main risk is with prescribing due to potential incorrect dose selection from the clinical systems.
Clinical effectiveness	*Established licensed product*	Ethinylestradiol is licensed for short-term treatment of symptoms of oestrogen deficiency, for osteoporosis prophylaxis if other drugs cannot be used (BNF section 6.6) and for the treatment of female hypogonadism and menstrual disorders.
Strength of evidence		Limited formal clinical evidence but established therapy and clinical practice.
Cost effectiveness or resource impact	*£*	Significant cost impact.
Place of therapy relative to available treatments	*1/2nd tier*	Second line to patches, if patient is allergic to or cannot tolerate patches.
National guidance and priorities	*NICE, MTRAC*	This drug is included in the British Society for Paediatric Endocrinology and Diabetes (BSPED) in their guidance statement for Hormone Supplementation for Pubertal Induction In Girls.
Local health priorities	*CCG views*	CCGs would not support primary care clinicians prescribing in this very small specialist group of patients.
Equity of access	*Equality assessment*	Testosterone undecanoate capsules are included in the APC formulary as a Red drug for induction of puberty in males.

Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	N/A

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	Approved as **Red**, for induction of puberty in female patients who cannot tolerate or are allergic to first-line patches. Rationale: Safety issues with prescribing in respect of potential for incorrect dose selection from clinical system, rarity of condition and regular specialist follow-up.
Implementation requirements:	
Implementation monitoring:	