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/0028- Revised December 2016
Drug name and formulations:		Ulipristal acetate (Esmya®) for intermittent use
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	As stated in NICE CG 44: Research is needed on the efficacy and safety of ulipristal acetate 5 mg over a period of more than 4 courses, compared with other uterus-sparing treatments.
Clinical effectiveness	*Established licensed product*	As per NICE CG 44: The current evidence suggests that ulipristal acetate 5 mg is an effective treatment for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter. The evidence covers a period of 4 courses (20 months).
Strength of evidence		Sufficient to get licence extension and support from NICE in CG 44 and SMC. RCTs comparing to placebo and active comparator GnRH analogue leuprorelin, which showed ulipristal was non-inferior to monthly injections of leuprorelin and superior to placebo.
Cost effectiveness or resource impact	*£*	Esmya® is approximately 17 times more expensive than tranexamic acid (monthly cost), 1.5 times more expensive than an average GnRH injection monthly cost, but less expensive than invasive surgical procedures.
Place of therapy relative to available treatments	*1/2nd tier*	In line with NICE CG 44.
National guidance and priorities	*NICE, MTRAC*	Revised NICE CG 44 on the management of Heavy Menstrual Bleeding published in August 2016. SMC has approved use 2nd line.
Local health priorities	*CCG views*	Potential costs are high; therefore commissioners would invite all Trusts wishing to use this agent to put forward a single business case which can be considered along with

		other health priorities.
Equity of access	*Equality assessment*	No issues
Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	If commissioners agree to fund it, an ESCA would be required.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	On the basis of NICE CG44, the APC would support the use of ulipristal acetate for intermittent use in line with licensed indication as AMBER with ESCA only if and when commissioners agree to fund it. Business case pending.
Implementation requirements:	
Implementation monitoring:	