

## 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
Drug name and formulations:		Ulipristal acetate (Esmya®) for intermittent use
Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	No long term safety data
Clinical effectiveness	<i>Established licensed product</i>	No long term effectiveness data. Moderately effective in the short term (reduction in size of fibroids and reduction in symptoms) No evidence whether surgical intervention is prevented or delayed.
Strength of evidence		Two small 20 week trials
Cost effectiveness or resource impact	£	The comparator tranexamic acid is £6.60 per month. Esmya® is approximately 17 times more expensive at £114.13 per month. There is no data from comparative/head to head trials.
Place of therapy relative to available treatments	<i>1/2<sup>nd</sup> tier</i>	N/A
National guidance and priorities	<i>NICE, MTRAC</i>	NICE clinical guidance on the management of Heavy Menstrual Bleeding is due April 2016. SMC has approved use 2nd line.
Local health priorities	<i>CCG views</i>	Potential costs are high; therefore commissioners will challenge if use is inappropriate. Not supported
Equity of access	<i>Equality assessment</i>	No issues
Stakeholder views	<i>Define wider groups to be engaged</i>	N/A
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	None

### Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	NOT APPROVED Rationale: lack of data on safety, effectiveness

	<p>and cost effectiveness. The clinician should also be reminded of the APC approved use (i.e one cycle prior to surgery) as there is evidence of creep beyond this approved use.</p>
<p>Formulary status (RAG) and rationale</p>	
<p>Implementation requirements:</p>	
<p>Implementation monitoring:</p>	