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/0017
Drug name and formulations:	Eslicarbazepine tablets 800mg (Zebinix®)

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Potential, but reduced risk of hyponatraemia. There are drug interactions (enhances metabolism of oral contraceptives). Warning about suicidal ideation in SPC.
Clinical effectiveness	*Established licensed product*	Established licensed product. Some evidence demonstrated against placebo similar to other AEDs
Strength of evidence		Weak. No head to head comparative studies presented. Placebo controlled trials were short duration (12 weeks)
Cost effectiveness or resource impact	*£*	NICE states: the addition of eslicarbazepine was associated with increased costs and better health outcomes (higher QALYs) than continuation of existing therapy alone (placebo), but with an expected incremental cost effectiveness ratio (ICER) of £53,585 per QALY which exceeds the NICE willingness to pay threshold.
Place of therapy relative to available treatments	*1/2nd tier*	Last line (up to 8th tier)
National guidance and priorities	*NICE, MTRAC*	An option for tertiary centres in NICE guidance.
Local health priorities	*CCG views*	MD expressed concerns that this sets precedence for any other AEDs. MD reminded the members that this is one drug of eight AED choices with limited evidence above other similar drugs. This effectively means all AEDs are put on the formulary. This is not a typical approach to formulary. In addition neurologists do use more than one AED to achieve the control required
Equity of access	*Equality assessment*	There are other options if this product was not available on the formulary.

Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	ESCA has been submitted, but needs to be revised if approved onto formulary.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	It was agreed that this drug would be amber with an ESCA plus additional steps for approval. The ESCA needs to be revised to reflect that approval is required by the Trust's decision making body (e.g. DTC), and it should reflect the place in therapy as tertiary recommended in line with NICE guidance
Implementation requirements:	ESCA with additional steps for approval. A revised version to come back to APC
Implementation monitoring:	