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/0059	
Drug name and formulations:	Brivaracetam (all formulations)	
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Comparable with other anti-epileptic drugs (AEDs). The most common adverse events with brivaracetam were somnolence, dizziness, headache and fatigue. Low potential for neuropsychiatric side effects. Neutropenia has been reported in 0.5% of brivaracetam patients- needs monitoring. Low interaction potential. No requirement for up-titration to reach therapeutic dose.
Clinical effectiveness	*Established licensed product*	Some evidence in placebo-controlled trials but no superiority to other agents. No additional benefit to levetiracetam.
Strength of evidence		Three RCTs versus placebo, but no trials against active comparators. Results from a Network Meta-Analysis (NMA),which included studies with brivaracetam, eslicarbazepine, perampanel, lacosamide and zonisamide, estimated that the probability of achieving seizure freedom was greater for brivaracetam than for the comparators, but the difference was not statistically significant. Brivaracetam treatment also gave the highest probability of achieving a 50% response rate, but the difference between brivaracetam and the comparators was not statistically significant.
Cost effectiveness or resource impact	*£*	Cost neutral compared to other 3rd-4th line agents , but vastly more expensive than generic levetiracetam (£129 per month vs £5 per month)
Place of therapy relative to available treatments	*1/2nd tier*	3rd- 4th line

National guidance and priorities	*NICE, MTRAC*	MTRAC July 2016 NICE Clinical Guideline 137 Epilepsies: diagnosis and management (2012), predates availability of brivaracetam. SMC accepted for restricted (July 2016). All these documents state that it must be initiated by specialist.
Local health priorities	*CCG views*	CCGs supportive if used as described in application (3rd line), and if rationale for choosing this agent in preference of other AEDs is clearly outlined to GPs if transfer to Primary Care deemed appropriate.
Equity of access	*Equality assessment*	N/A
Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	Would require ESCA if accepted, but need to include a section to outline rationale as mentioned above. RICaD not appropriate for this agent.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	**Oral formulations: AMBER with ESCA. Initiation by Tertiary Epilepsy Consultant only.** **Injection: Red –hospital only**
Implementation requirements:	ESCA needs to include a section to outline rationale for choosing this agent in preference of other 3rd line AEDs.
Implementation monitoring:	