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/0057
Drug name and formulations:		Pramipexole MR tablets (all strengths)
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Same side effect profile and interactions as the pramipexole immediate release (IR) formulation.
Clinical effectiveness	*Established licensed product*	Non- inferior to IR formulation
Strength of evidence		Reasonably strong: meta-analysis from 4 trials confirmed MR product was superior to placebo but no better (non-inferior) than its IR counterpart.
Cost effectiveness or resource impact	*£*	Significantly more expensive than IR pramipexole. Pramipexole MR is available as branded Mirapexin® and a couple of branded generics (e.g. Pipexus®) but costs for both are still considerable compared to immediate release, and could result in an additional £2K-4K per patient per year compared to IR formulation.
Place of therapy relative to available treatments	*1/2nd tier*	Equivalent to IR, marginal benefit for improved compliance. Formulary status would remain amber as is the IR formulation. The initiation would be done within secondary or tertiary care.
National guidance and priorities	*NICE, MTRAC*	NICE guidelines are currently being reviewed and updated, but there has been some delay in publishing these. SMC has accepted for use in 2009, when only branded pramipexole IR and MR were available and costs were equivalent.
Local health priorities	*CCG views*	CCGs are not supportive in view of high cost, concerns about prescribing creep and with no proven clinical benefit over current formulary option.

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, in line with current formulary options.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	**NOT APPROVED**. Rationale: significant cost impact on health economy with no clinical benefit over current formulary options. There is already a modified–release dopamine agonist on the formulary which is considerably more cost-effective. This is in line with decision reached for opicapone in May 2017.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	