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/0055	
Drug name and formulations:	Opicapone 50mg capsules (Ongentys®)	
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Similar side effect profile to entacapone. The most common adverse reactions reported were central nervous system disorders with dyskinesia reported as very common. Common ADRs included dizziness headache and somnolence. No evidence of liver toxicity associated with tolcapone. Black triangle drug ▼, subject to additional monitoring.
Clinical effectiveness	*Established licensed product*	BIPARK I found that opicapone, as an adjunct to levodopa, was more effective than placebo at reducing off time in people with PD (mean difference of 60.8 minutes). Improvements in on time without troublesome dyskinesia were also seen in people treated with opicapone (mean difference of 62.6 minutes compared with placebo). Opicapone was shown to be non-inferior to entacapone for reducing off time. Clinician reported 26mins less off time with opicapone vs entacapone, however trial was under powered to show superiority, and only confirmed non-inferiority.
Strength of evidence		RCTs confirmed non-inferiority compared to entacapone. Data suggesting trend towards superiority is yet unpublished.
Cost effectiveness or resource impact	*£*	Significantly more expensive than generic entacapone. Opicapone only available as a single agent, no combination product; patient would still need to take multiple doses of levodopa.
Place of therapy relative to available treatments	*1/2nd tier*	Although manufacturers recommend second-line therapy to entacapone, specialist suggested it

		could be used first line which would have a significant cost impact on health economy.
National guidance and priorities	*NICE, MTRAC*	NICE Clinical Guideline (CG35) published in June 2006 is being updated, and expected to be published in June 2017. It is not anticipated to differentiate between the 3 available COMT inhibitors.
Local health priorities	*CCG views*	CCGs are not supportive in view of high cost with no proven clinical benefit over current formulary option. Also concerned about prescribing creep.
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, in line with current formulary option.

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 proven clinical benefit over current formulary option.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	