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/0061	
Drug name and formulations:	Opicapone 50mg capsules (Ongentys®)	
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Slightly different side effect profile and GI tolerance 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 Data suggesting trend towards superiority is yet unpublished.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*	Second-line therapy to entacapone, in patients who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy is being considered.

National guidance and priorities	*NICE, MTRAC*	Updated NICE Guideline (NG71) was published in July 2017 and recommends COMT inhibitors (no differentiation between the 3 available products) as an option alongside dopamine agonists and MAO-B inhibitors for adjuvant treatment of motors symptoms after discussing the potential benefits and harms of the different drug classes (new 2017). MTRAC's opinion is that opicapone would be suitable for prescribing in primary care following initiation in secondary care and that some patients would benefit from the additional option offered by opicapone, especially those in whom entacapone is contraindicated, poorly tolerated or poorly effective.
Local health priorities	*CCG views*	CCGs would only support if initiated by PD specialists with clear patient selection criteria and successful review following 3 months' treatment before transferring prescribing to primary care under shared care.
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. ESCA should include rationale for patient selection, 3 month's prescribing retained by specialist and successful review before transfer of care.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	**Approved as Amber with ESCA**. Second-line therapy to entacapone, in patients who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy is being considered.
Implementation requirements:	ESCA to be developed by PD specialist with criteria outlined by committee.
Implementation monitoring:	