South East London Area Prescribing Committee
Formulary recommendation

Reference:	**087**
Intervention:	**Opicapone adjunctive therapy for the management of end-of-dose motor fluctuations in adults with Parkinson's disease** (Opicapone is a medicine used in Parkinson's disease under the class of catechol-O-methyltransferase [COMT] inhibitors)
Date of Decision:	**June 2018**
Date of Issue:	**July 2018**
Recommendation:	**Amber 2 – initiation and first prescription supplied by the specialist neurology team**
Further Information	• Opicapone (Ongentys®) is accepted for use within its licence as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors (DDCI) in adults with Parkinson's disease and end-of-dose motor fluctuations. • Entacapone is the first line COMT-inhibitor of choice. Opicapone is restricted for use as a **2nd line** COMT-inhibitor after entacapone where: - Entacapone on its own or in combination preparations with levodopa is not appropriate due to inadequate control of symptoms or intolerance/adverse effects - There are risks from polypharmacy/multiple dosing and the combination products (e.g. Stalevo or Sastravi) have been trialled but the issues of concordance remain (see local guidance) - For patients with swallowing difficulties, options such as crushing the tablets have been considered but would not be appropriate • Switching of stable patients on treatment with entacapone over to opicapone is **not** supported by this recommendation. • Opicapone is a once daily COMT-inhibitor administered at a dose of 50mg daily. It should be taken at bedtime at least one hour before or after levodopa combinations. • Please also refer to local guidance on the management of symptoms in people with Parkinson's disease with motor complications, which sets out the place in therapy for opicapone.
Shared Care/ Transfer of care required:	N/A – continuation in primary care under an individual management plan (for example, a detailed clinic letter) between specialist and the GP.
Cost Impact for agreed patient group	• Assuming the branded generic would always be used where the combination tablets are prescribed, depending on the dose, the cost difference between entacapone and opicapone regimens varies between approximately £700 and £1,000 per patient per annum. • In 2016 the NHS in England spent £11.8m on 21.3 million doses of entacapone containing products. If it is assumed that the average daily dose is 6 tablets per day, this equates to approximately 3.55 million days of entacapone therapy in England, or approximately 6,500 days of entacapone therapy per 100,000 population. This equates to approximately 18 people per 100,000 population being on entacapone. • Based on the 2nd line place in therapy, if it is assumed that 50% of people (9 people per 100,000 population) might be eligible for treatment with opicapone, this would result in an additional cost (vs. entacapone) of up to £9,000 per 100,000 population. • This equates to a potential additional cost across SEL of £162,000 (excluding VAT). • Alternatively, information provided by the manufacturer for the NICE evidence summary on opicapone estimates that by 2019 almost 3,000 people will be treated with opicapone in England or ~5.5 people per 100,000 population. This equates to ~100 people across SEL and would result in a potential additional cost of up to £100,000 for SEL. • The cost impact is therefore estimated to be between £100K to £162K for SEL (exc. VAT).

Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor use and submit usage data and audit reports (against this recommendation, in particular against the initiation criteria, and the guidance) upon request to the APC.
	CCGs: • Monitor ePACT data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Parkinson's disease in the over 20's: Diagnosis and management. National Institute for Health and Care Excellence Clinical Guideline 35 (2006). 2. Parkinson's disease: diagnosis and management – Draft for consultation October 2016. National Institute for Health and Care Excellence. Available online here (accessed 08/07/2017) 3. Ongentys® (opicapone) Summary of Product Characteristics. Available online at: http://www.medicines.org.uk/emc/medicine/32365 (accessed 22.06.18, date of revision of text 06/2016) 4. Devos D, Moreau C. Opicapone for motor fluctuations in Parkinson's disease. Lancet Neurology 2016 15 p127-18 5. Ferreira J, Lees A, Rocha J et al. Opicapone as an adjunct to levodopa in patients with Parkinson's disease and end-of-dose motor fluctuations: a randomised, double-blind, controlled trial. Lancet neurology 2016 15 p154-165. 6. Lees A, Ferreira J, Rascoi O et al. Opicapone as adjunct to levodopa therapy in patients with Parkinson disease and motor fluctuations. JAMA Neurology 2017 74 (2) p197-206 7. Ongentys® (opicapone) European Public Assessment Report 2016. Available online at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002790/WC500209538.pdf (accessed 10/07/2017) 8. Evidence Summary 9. Parkinson's disease with end-of dose motor fluctuations: opicapone. National Institute for Health and Care Excellence Evidence Summary (ES9) 2017. Available online at: https://www.nice.org.uk/advice/es9 (accessed 10/07/2017) 9. British National Formulary. Available online at: https://www.medicinescomplete.com (accessed 10/07/2017) 10. Prescription Cost Analysis, England - 2016. Available online at: http://www.content.digital.nhs.uk/catalogue/PUB23631 (accessed 10/07/2017) 11. Opicapone (Ongentys®). All Wales Medicines Strategy Group 2016 (Ref 911)

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on the APC website.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS.