AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Opicapone (Ongentys®▼) as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations

February 2019

ONE WALES INTERIM COMMISSIONING DECISION

Opicapone (Ongentys®▼) as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations

Date of advice: February 2019

The following Interim Pathways Commissioning Group (IPCG) recommendation has been endorsed by health board Chief Executives.

Using the agreed starting and stopping criteria, opicapone (Ongentys®▼) can be made available within NHS Wales as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations. Opicapone is restricted for use only after failure of entacapone, or in patients who cannot tolerate entacapone or have concordance issues. This recommendation applies only in circumstances where the approved commercial arrangement price is applied.

This advice will be reviewed after 12 months or earlier if new evidence/information becomes available.

Advice is conditional on subsequent Health Technology Assessment advice from AWMSG or NICE becoming available.

Clinician responsibility
Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Interim Commissioning decision.

Health board responsibility
Health boards will take responsibility for implementing One Wales Interim Commissioning decisions and ensuring that a process is in place for monitoring clinical outcomes.

One Wales advice promotes consistency of access across NHS Wales.

Start and stop criteria for opicapone (Ongentys®▼) as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations

Start criteria:
Opicapone (Ongentys®▼) may be commenced in individuals as an adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end of dose motor fluctuations who cannot be stabilised on those combinations when used in accordance with the eligibility criteria described below.

The following individuals will be eligible for treatment with opicapone:

1. Those with wearing off, intolerance to or not benefitting from entacapone
2. Those suitable for entacapone treatment but have significant drooling, significant diarrhoea or urinary incontinence
3. To optimise symptoms of those with advanced Parkinson's disease who may need apomorphine therapy, deep brain stimulation (DBS) or Duodopa® and wish to delay non oral therapies
4. Those who find it difficult to swallow combination formulations of entacapone/levodopa
5. To improve drug concordance in a small number of people who have large pill burden by taking once daily COMT inhibitor (mainly to improve morning akinesia)

Opicapone (Ongentys®▼) is appropriate for initiation by a specialist in secondary care, once the patient is stabilised opicapone may be prescribed in primary care.

Stop criteria:
1. Lack of benefit with opicapone according to clinician and patient global impression
2. Intolerance to opicapone
3. Development of significant dyskinesia following introduction of opicapone which can't be managed by reduction of levodopa
4. Development of significant dementia or neuropsychiatric symptoms

One Wales Interim Commissioning Process
Interim Pathways Commissioning Group (IPCG) summary of decision rationale

Medicine: **opicapone (Ongentys®▼)**
Indication: **adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations**
Meeting date: **28th January 2019**

Criteria	IPCG opinion
Clinical effectiveness	IPCG accepts the two BIPARK phase III studies as making the case for opicapone being clinically effective and non-inferior to entacapone. IPCG accepts the proposed place in therapy, for use as a second-line catchecol-O-methyltransferase (COMT) inhibitor after failure of entacapone, or in patients who cannot tolerate entacapone or have concordance issues.
Cost-effectiveness	IPCG notes that there was no cost effectiveness evidence presented. IPCG acknowledges the company's proposed health economic study and outcomes will be collected by clinicians.
Budget impact	IPCG accept apomorphine as the most likely medicine to be deferred by opicapone. The estimated budget impact demonstrates that the addition of opicapone as a treatment option would be cost saving compared with apomorphine. The IPCG considers this plausible. IPCG notes that there is little difference in list price between opicapone in combination with levodopa/carbidopa and Stalevo (entacapone with levodopa/carbidopa).
Other factors	Opicapone is expected to delay progression to more expensive and/or invasive treatments such as apomorphine. Some patients find it very difficult to swallow Stalevo due to its size and shape. Taking entacapone separately increases tablet burden as it may be required up to ten times a day. Opicapone is taken once daily and offers a simplified regimen. There is a small group of patients who experience incontinence and drooling as a consequence of the Parkinson's disease. Entacapone is excreted in bodily fluids as a deep orange colour. Opicapone does not discolour bodily fluids and therefore is a suitable alternative for this group of patients. Tolcapone is associated with rare but potentially fatal acute liver injury (see SmPC), requires monitoring of liver function tests, and is now rarely used in practice.
Final recommendation	Opicapone should be made available in Wales restricted for use only after failure of entacapone, or in patients who cannot tolerate entacapone or have concordance issues. This is contingent on the marketing authorisation holder submitting for appraisal to AWMSG in 12 to 18 months.
Summary of rationale	Clinical efficacy has been suitably demonstrated. Opicapone may delay progression to more invasive/expensive treatment options. IPCG understands that the company will be making a submission to AWMSG for health technology assessment in 12 to 18 months.