NHS
Pan Mersey
Area Prescribing Committee

OPICAPONE (Ongentys® ▼) for Parkinson's Disease

The Pan Mersey Area Prescribing Committee recommends the prescribing of OPICAPONE (Ongentys® ▼), following specialist recommendation, as add-on therapy in adult patients with Parkinson's disease.

AMBER following specialist recommendation

Opicapone is a once daily peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor that is indicated as adjunctive therapy to levodopa preparations in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on levodopa with a DOPA decarboxylase inhibitor.

Entacapone is the Pan Mersey formulary COMT inhibitor of choice and is recommended as the first line option for patients who require adjunctive treatment with a COMT inhibitor. It is available as a combination product with levodopa and carbidopa, or as an individual component that can be administered with co-careldopa or co-beneldopa preparations.

The Pan Mersey Area Prescribing Committee recommends the prescribing of opicapone, following specialist recommendation only, in patients who have failed to respond to, or are intolerant of, entacapone, and in whom consideration is being given to prescribing tolcapone

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

SUPPORTING INFORMATION

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Effectiveness [1,2,3,4]

The efficacy of opicapone was assessed in two phase-3 double-blind, placebo-controlled studies, one of which also included an active comparator arm. The trials included 1027 patients with Parkinson's disease who were receiving treatment with a levodopa-containing preparation and experiencing end-of-dose motor fluctuations. The primary efficacy endpoint in both studies was change from baseline to end of study treatment in absolute time in the off state, as assessed by paper patient diaries. In both studies, opicapone 50mg daily was superior to placebo for this outcome and this effect was sustained throughout the 1-year open-label extension study. In the active comparator study, opicapone 50mg was shown to be non-inferior to entacapone 200mg.

Safety[1,5]

Opicapone is contraindicated in patients with phaeochromocytoma, paraganglioma, or other catecholamine-secreting neoplasms; a history of neuroleptic malignant syndrome and/or non-traumatic rhabdomyolysis; concomitant use of MAO-A or MAO-B inhibitors, other than those used in the treatment of Parkinson's disease.

The most commonly reported adverse effect in phase-3 clinical trials was dyskinesia, which was more common in treatment arms than with placebo, and slightly higher than for entacapone. Other common side effects include abnormal dreams, hallucinations, visual hallucinations, insomnia, dizziness, headaches, somnolence, orthostatic hypertension, dry mouth, constipation, vomiting, muscle spasms and increased blood creatine phosphokinase levels. For full prescribing information, consult the SPC.

Cost[6]

Annual cost of treatment and comparators:

Opicapone 50mg daily: £1142

Entacapone 200mg tds, up to 2g/day: £120-400

Tolcapone 100-200mg TDS: £1042-2085

Patient numbers are low. Total spend for Pan Mersey APC CCGs April 2018-March 2019 = £23,289; this equates to approx. £1,171 per 100,000 population.

Patient factors[5]

No dosage adjustments are required in elderly patients, renal impairment or mild hepatic impairment (Childs-Pugh class A).

Caution, and possible dose reduction, is recommended in patients with moderate hepatic impairment (Childs-Pugh class B) and treatment is not recommended in patients with severe (Childs-Pugh class C) hepatic impairment.

Prescribing information[5]

The recommended dose of opicapone is 50mg, taken once daily at night, at least one hour before or after levodopa-containing preparations. The capsules should be swallowed whole with water. Opicapone enhances the effect of levodopa; however, this may be beneficial as these patients are requiring a step-up of their treatment. Patients should report any new adverse effects and advice should be obtained from the initiating clinician about dose adjustments. Patients and care-givers should be made aware that impulse control disorders including pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating or compulsive eating may occur with opicapone. Treatment should be reviewed by the specialist if these effects are noticed.

Implementation notes

Treatment should only be recommended by specialists in the management of Parkinson's disease, which may include, but is not limited to, neurologists, gerontologists or GPs with a specialist interest in Parkinson's disease. It is the responsibility of the specialist team to provide clear, detailed information about the treatment regimen to the GP on initiation and when dose adjustments are made. Dose adjustments remain the responsibility of the specialist team throughout treatment. It is the initiating clinician's responsibility to counsel patients about potential impulse control disorders.

SUPPORTING INFORMATION

References

1. European Medicines Agency. EPAR: assessment report: Ongentys, 28 April 2016. Accessed 31 May 2019.
2. Ferreira JJ, Lees A, Rocha J-F, 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 Neurol, 2016; 15: 154-65
3. Lees A.J.; Ferreira J.; Rascol O.; et al. Opicapone as adjunct to levodopa therapy in patients with Parkinson disease and motor fluctuations a randomized clinical trial. JAMA Neurology; Feb 2017; 74: 197-206
4. NICE Evidence summary. Parkinson's disease with end-of-dose motor fluctuations: opicapone 21 March 2017. Accessed 03 June 2019
5. Bial Pharma UK Ltd. Summary of Product Characteristics: Ongentys® ▼ 50mg hard capsules (last updated 19 February 2019). Accessed 23 July 2019.
6. NHS Business Services Authority. dm+d browser. Accessed 23 Jul 2019.