

Enclosure no:	2/AWMSG/0524
Agenda item no:	6 – NMG Preliminary Appraisal Recommendation Opicapone (Ongentys®)
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Opicapone (Ongentys®) 50 mg hard capsule

Indication under consideration:

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

Limited submission by Bial – Portela & C^a, S.A

Date: Wednesday 10th April 2024

NMG advice to AWMSG:

Opicapone (Ongentys®) is recommended as an option for use within NHS Wales as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

Additional note(s):

- This advice incorporates and replaces the existing AWMSG recommendation for Opicapone (Ongentys®) (Adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations, restricted within the licensed indication for use after failure of entacapone, or in patients who cannot tolerate entacapone.) (AWTTC reference number 911, originally published March 2021).

In reaching the above recommendation NMG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 5285), which includes the AWMSG Secretariat Assessment Report (ASAR) and the applicant company's response to the ASAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

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New Medicines Group Preliminary Appraisal Recommendation
Opicapone (Ongentys®). Reference number 5285. April 2024