Enclosure no:	**2/AWMSG/0423**
Agenda item no:	5 – NMG Preliminary Appraisal Recommendation Levodopa-carbidopa-entacapone (Lecigon®)
Author:	New Medicines Group
Contact:	Tel: 029 218 26900 E-mail: awttc@wales.nhs.uk

Levodopa-carbidopa-entacapone (Lecigon®) 20 mg/ml + 5 mg/ml + 20 mg/ml intestinal gel

Indication under consideration:
Levodopa-carbidopa-entacapone (Lecigon®) for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results.

Submission by Britannia Pharmaceuticals Ltd

Date: Wednesday 1st March 2023

NMG advice to AWMSG:

Levodopa-carbidopa-entacapone (Lecigon®) is recommended as an option for restricted for use within NHS Wales. Levodopa-carbidopa-entacapone (Lecigon®) should be restricted for use in the following subpopulation within its licensed indication for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results:

Patients not eligible for deep brain stimulation.

Levodopa-carbidopa-entacapone (Lecigon®) is not recommended for use within NHS Wales outside of this subpopulation.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Additional note(s):

- NMG considered Levodopa-carbidopa-entacapone (Lecigon®) as an orphan-equivalent medicine according to the criteria in the AWMSG appraisal process for a medicine for a rare disease.

In reaching the above recommendation NMG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4871), 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.