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Company Response to the Preliminary Appraisal Recommendation Levodopa-carbidopa-entacapone (Lecigon®) 20 mg/ml + 5 mg/ml + 20 mg/ml intestinal gel

The following response was communicated via email from Britannia Pharmaceuticals:

AWMSG Submission – LECIG (Lecigon®)
Response to PAR – 17.03.23

Summary

Britannia would like to thank the New Medicines Group (NMG) for their consideration of the company's AWMSG submission and for producing the Preliminary Appraisal Recommendation (PAR). Britannia welcomes the NMG's evaluation that levodopa, carbidopa, entacapone intestinal gel (LECIG) meets the AWMSG orphan equivalent criteria and are pleased to read that LECIG is preliminary recommended for use within the NHS Wales. If recommended by the AWMSG, LECIG will offer patients with advanced Parkinson's disease (PD) an additional intestinal gel (IG) treatment option with a more convenient method of administration, at reduced costs to the AWMSG.

Wider benefits and budget impact of LECIG

As demonstrated in Form B, it is expected that LECIG will have comparable clinical outcomes to levodopa, carbidopa intestinal gel (LCIG), but at reduced costs. Beyond this, Britannia requests that the AWMSG Committee consider the following points relating to the wider benefits and budget impact of LECIG in their deliberations. Britannia hopes that these points will enable the AWMSG to recommend LECIG, as an orphan-equivalent product, for the treatment of patients with advanced PD, as per Britannia's positioning of LECIG in Form B:

- IGs offer patients in the advanced stage of disease increased stability in their levodopa dose, avoiding the peaks and troughs of disease activity which are common with oral and transdermal medications.[1] LECIG therefore provides patients an additional IG formulation that offers patient value by allowing more consistent control of disease symptoms
- LECIG is due to be administered via a new Crono LECIG pump which is both over half the size and significantly lighter than the existing pump used for LCIG. As the Smith Medical CADD 1400 pump used for LCIG may be viewed by patients as 'large, heavy and bulky', it is anticipated the Crono LECIG pump will offer patients the value of increased portability, as well as being discrete to wear.[2] The results of a real-world evidence (RWE) study of LECIG use in clinical practice found that all patients previously treated with

LCIG regarded the Crono LECIG pump size to be an improvement relative to the standard pump used with LCIG.[3] The reduced pump size has the potential to decrease the burden on patients when they are performing daily activities

- As well as the increased portability of the device, the Crono LECIG pump offers improved accuracy in the infusion of the drug (+/- 3% versus +/- 10%). This, combined with the fact the device also includes a programmable multiple flow rate, allows patients to have increased control and independence over the amount of drugs entering their body.[4] The majority of patients previously treated with LCIG in the RWE study regarded the new pump to be improved with respect to user-friendliness (81.8% improved; 18.2% unchanged) and with respect to changing cassette/syringe (72.7% improved; 27.3% unchanged)[3]
- Both ongoing patients and patients initiating LECIG in Wales will have access to a patient support service, funded by Britannia Pharmaceuticals. The patient support service offers a complete package of care for patients and physicians including a 24-hour technical helpline as well as training and educational resources to support with both treatment initiation and monitoring. Additionally, the support service provides a dedicated nurse service which offers 1:1 specialist care and support in hospitals and homes across the UK by PD nurses. The dedicated nurse service is of particular importance as Britannia has understood, during other UK HTA processes, that the nursing support currently available around existing comparator treatment is insufficient to meet patient needs
- Finally, given LECIG is anticipated to be associated with lower acquisition costs compared with LCIG, with all other costs remaining equal, LECIG is associated with cost-savings in the budget impact analysis, which increase from Years 1 through to Year 5 following the introduction of LECIG in Welsh clinical practice

Britannia hopes that the above points will support the AWMSG's decision to recommend LECIG as a treatment option for patients in Wales with advanced PD with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results, in patients not eligible for DBS. This recommendation would help to address the unmet clinical need for a treatment option that is able to deliver comparable levodopa plasma levels, at a reduced administered levodopa dose, with a more convenient method administration and at a reduced cost to the AWMSG.

References

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2. Scott B, Nyholm D. Patient-perceived retrospective outcome of duodenal levodopa infusion in advanced Parkinson's Disease. Eur Neurol J 2010;2:3-10.
3. Öthman M, Widman E, Nygren I, et al. Initial Experience of the Levodopa–Entacapone–Carbidopa Intestinal Gel in Clinical Practice. Journal of Personalized Medicine 2021;11:254.
4. Lokk J, Delbari A. Clinical aspects of palliative care in advanced Parkinson's disease. BMC palliative care 2012;11:1-8.
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