HSE Drugs Group – November 2022 Minutes

Meeting 2022.10: Tuesday 8th November 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the October 2022 meeting were considered and approved.

2. Confidentiality forms

It had previously been agreed that all members (including public servants) would sign confidentiality forms (once off action).

3. Matters arising / Update on Medicines considered at previous meeting

i. The October 2022 Drugs Group relevant recommendations had been approved by the HSE Executive Management Team (EMT).

ii. Following a discussion regarding further Drugs Group meeting capacity, members were reminded to confirm their capacity to attend an additional Drugs Group meeting before the end of the year.

iii. The Group were advised that 47 new medicines / new uses of existing medicines had been approved by the HSE to date in 2022. A number of these medicines were approved on a cost-minimisation basis following NCPE assessment and HSE CPU commercial negotiation processes.

4. Declaration of Interests / Nil Interest

One member declared a potential interest in relation to item 5. ii (Delta-9-tetrahydrocannabinol/Cannabidiol for multiple sclerosis related spasticity) and would abstain from voting on this medicine.

5. Medicines for Consideration

i. 22026 Ozanimod for ulcerative colitis

The Drugs Group considered Ozanimod (Zeposia®) for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. The Group noted that Ozanimod, a S1P receptor modulator represented a new, oral treatment option for ulcerative colitis that appears to offer a relatively tolerable safety profile. The Group considered the broad range of treatment options reimbursed for ulcerative colitis including biosimilar TNF-α inhibitors and alternative oral treatments. Following consideration of the available clinical evidence and the commercial offer, the Group noted that Ozanimod would now represent [redacted] for ulcerative colitis if reimbursed [redacted] The Group unanimously recommended in favour of reimbursement of Ozanimod under High Tech arrangements for ulcerative colitis providing reimbursement is restricted to use as a subsequent line of therapy following treatment with a lower cost biological disease modifying anti-rheumatic drug (bDMARD).

ii. 22027 Delta-9-tetrahydrocannabinol/Cannabidiol for multiple sclerosis related spasticity

The Drugs Group considered Delta-9-tetrahydrocannabinol (THC) / Cannabidiol (CBD) (Sativex®) as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Despite currently available pharmacological treatments for MS related spasticity, the Group acknowledged the need for new treatment options with different modes of action. The Group reviewed and discussed the clinical evidence available for Sativex® including the trials (GWSP0604 and SAVANT) which informed the pharmacoeconomic analysis. At list price, Sativex®, as an add on therapy to standard of care, was considered cost-effective under the Applicant's base case but not cost-effective incorporating the NCPE's preferred base case assumptions at the conventional willingness-to-pay threshold of €45,000/QALY. Notwithstanding the improvement in cost-effectiveness and affordability following consideration of the proposed commercial offer, the Drugs Group noted Sativex® [redacted]. A patient interest group submission from MS Ireland was considered in the overall deliberations of the Drugs Group. The Group also noted the Ministerial Licensing Application Process for patients to avail of Cannabis-based treatments and the availability of Cannabis-based products under the Medical Cannabis Access Programme (MCAP). Following consideration of the totality of evidence, including the substantial unmet need for patient access to a proven, efficacious, safe and licensed THC/CBD treatment in Ireland, the Drugs Group, by majority, recommended in favour of reimbursement of Sativex® subject to the establishment of a managed access protocol.

iii. 22028 Relugolix / Estradiol / Norethisterone acetate for uterine fibroids

The Drugs Group considered Relugolix with Estradiol and Norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The Group reviewed the evidence from the clinical development program for Ryeqo®. It was noted that the reduction in uterine fibroid volume was not statistically significant in comparison with placebo. The Group also considered the lack of an active comparator in LIBERTY 1 and 2 (and extension studies) as a limitation in determining the relative clinical efficacy benefit versus available comparators. The annual cost of Ryeqo® is substantially more expensive than all other comparators for the treatment of uterine fibroids including the treatment cost associated with Ulipristal acetate and GnRH agonists (6 months and 2 x 3 months treatment duration comparison respectively). The Group also noted that the budget impact estimates are subject to considerable uncertainty. The Drugs Group unanimously did not support reimbursement of Ryeqo® on the basis of the available clinical evidence and the price premium relative to alternative pharmacological treatment options.

iv. 22003 Olaparib for metastatic castration resistant prostate cancer

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the December 2022 meeting.

v. 22029 Encorafenib for metastatic colorectal cancer

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the December 2022 meeting.

vi. 22030 Trifluridine / Tipiracil for metastatic gastric cancer

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the December 2022 meeting.

6. AOB

The HSE received an application for pricing and reimbursement of Caplacizumab (Cablivi®) in March 2022 for the treatment of adults and adolescents of 12 years of age and older weighing at least 40 kg experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression. Following the NCPE rapid review assessment, a full Health Technology Assessment (HTA) was recommended and subsequently commissioned to assess the clinical effectiveness and cost effectiveness of Caplacizumab compared with the current standard of care. The applicant submitted a commercial offer for Caplacizumab to the CPU on the basis they were not in a position to submit a HTA dossier at that time. The Drugs Group unanimously agreed that a full HTA should be conducted in line with standard processes and consideration of a commercial proposal in advance of same would not be considered by the Group.

Appendix 1: Members Present on Microsoft Teams

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Mr Shaun Flanagan	Primary Care Reimbursement Service (Assistant National Director)	Apologies received
Ms Aoife Kirwan	Public Interest Member	In attendance
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann for Professor Risteárd Ó Laoide	Chief Pharmacist, National Cancer Control Programme for National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Dr Philip Crowley	National Director for Quality Improvement (Medical Doctor)	Apologies received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Post Vacant	Office of Nursing & Midwifery Services (Director of Nursing)	n/a
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	In attendance
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Post Vacant	Acute Operations Division (Assistant National Director)	n/a
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	Apologies received
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

In attendance (non-voting):
Dr Lesley Tilson (NCPE)

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS