HSE Drugs Group – November 2024 Minutes
Meeting 2024.10: Tuesday 12th November 2024, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the October 2024 meeting were considered and approved.

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

i. The Chair emphasised the importance of all members (or nominated alternates where relevant) prioritising Drugs Group meeting attendance.

ii. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from the October 2024 meeting progressed to the HSE Senior Leadership Team (SLT) for consideration had been supported.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Pembrolizumab in combination with Lenvatinib for endometrial carcinoma (NCPE HTA ID: 22006)

The Drugs Group considered Pembrolizumab (Keytruda®), in combination with Lenvatinib (Lenvima®), for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation. The Group acknowledged the significant unmet need for new therapies in this setting. Pembrolizumab + Lenvatinib represents the first combination of a PD-1 inhibitor plus VEGF inhibitor licensed for the treatment of advanced or recurrent endometrial cancer after platinum-based therapy. The Group reviewed the clinical evidence from the pivotal KEYNOTE-775 trial, noting the significant overall survival benefit for Pembrolizumab + Lenvatinib versus chemotherapy. The Drugs Group considered a patient organisation submission from the Irish Society for Gynaecological Oncology in their deliberations alongside advice from the National Cancer Control Programme Technology Review Committee (NCCP TRC). In reviewing the pharmacoeconomic evidence, the Group noted the ICER (at list price) ranged from €121,749/QALY (applicant base case) to €197,770/QALY (NCPE adjusted base case) for Pembrolizumab + Lenvatinib versus treatment of physician's choice (TPC). The Group recognised the reimbursement challenges associated with combination regimens with patented component therapies from individual manufacturers. The Group reviewed the impact of individual commercial proposals submitted for Pembrolizumab and Lenvatinib. It was acknowledged that the marketing authorisation holder of Lenvatinib (Lenvima®) separately engaged in commercial negotiations with the HSE for this medicine in a bid to improve the overall cost-effectiveness of this expensive combination regimen. Notwithstanding the improvement in cost effectiveness (incorporating the commercial proposals), the Group noted both cost effectiveness estimates remained above the conventional €45,000/QALY willingness to pay threshold. The median overall survival benefit of Pembrolizumab + Lenvatinib versus chemotherapy was discussed against the backdrop of cost effectiveness, affordability and opportunity cost. Following protracted deliberations, the Group, by majority, did not recommend in favour of reimbursement, noting that reimbursement of this combination regimen did not represent an optimum use of limited HSE resources.

ii. Pegcetacoplan for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) (NCPE HTA ID: 21064)

The Drugs Group considered Pegcetacoplan (Aspaveli®) for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) in adult patients who are anaemic after treatment with a complement C5 inhibitor for at least three months. The Group discussed the rapidly evolving PNH treatment landscape as evidenced by an increase in pricing and reimbursement applications in this space (including biosimilar Eculizumab). The Group acknowledged the need for additional therapies in treatment experienced patients seeking enhanced PNH control. The Group reviewed the clinical and economic evidence, noting a number of limitations and uncertainties therein. A patient organisation submission from PNH Support was also considered by the Drugs Group in their deliberations. It was acknowledged that Pegcetacoplan, an orphan medicine, represented a treatment option for self-administration. Following extended and protracted deliberations, the Group recommended reimbursement of Pegcetacoplan under High Tech arrangements, subject to an improved commercial offering [redacted] and a managed access protocol. The Group further recommended that a review of the PNH treatment landscape be conducted after 18 months with a view to identifying greater efficiencies in this high cost area.

iii. Fenfluramine for Dravet Syndrome (NCPE HTA ID: 23048)

The Drugs Group considered Fenfluramine (Fintepla®) for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. The Group reviewed the clinical and economic evidence in detail as well as patient organisation submissions from Epilepsy Ireland & Dravet Syndrome Ireland. The Group acknowledged the significant impact of Dravet syndrome on patients' and carers' quality of life and the need for alternative treatment options for enhanced seizure control. In reviewing the pharmacoeconomic evidence, the Group noted the commercial proposal [redacted]. The commercial proposal included a significant transparent reduction in the price-to-wholesaler, which was welcomed by the Group. Following deliberations, the Group unanimously recommended in favour of reimbursement of Fenfluramine (Fintepla®), for this indication, under High Tech arrangements, on the basis of the significant unmet need, the clinical evidence, and substantial improvement in cost effectiveness.

iv. Fenfluramine for Lennox-Gastaut Syndrome (NCPE HTA ID: 23051)

The Drugs Group considered Fenfluramine (Fintepla®) for the treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-seizure medicines for patients 2 years of age and older. The Group reviewed the clinical and economic evidence in detail as well as patient organisation submissions from Epilepsy Ireland & Dravet Syndrome Ireland. The Group acknowledged the significant impact of Lennox-Gastaut syndrome on patients' and carers' quality of life and the need for alternative treatment options for enhanced seizure control. In reviewing the pharmacoeconomic evidence, the Group noted the commercial proposal [redacted]. The commercial proposal included a significant transparent reduction in the price-to-wholesaler, which was welcomed by the Group. Following deliberations, the Group unanimously recommended in favour of reimbursement of Fenfluramine (Fintepla®), for this indication, under High Tech arrangements, on the basis of the significant unmet need, the clinical evidence, and substantial improvement in cost effectiveness.

AOB.

i. The Chair requested that all members review the circulated draft revisions to the HSE Drugs Group Terms of Reference in advance of the next meeting.

ii. The Chair welcomed the HSE Senior Leadership Team approved appointment of Dr Kevin Kelleher as an additional member to the HSE Drugs Group.

iii. Drugs Group members were advised that targeted communications pertaining to specific pricing and reimbursement applications for consideration by the Drugs Group should be forwarded to the CPU (as the HSE Drugs Group secretariat).

iv. Drugs Group members were advised that an in person meeting would be held in December 2024. A videoconferencing option would be facilitated for those who could not physically attend.

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)	In attendance
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)	In attendance
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Ms Mary Ruth Hoban	Assistant Director of Nursing and Midwifery (Prescribing) HSE West	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Carol Ivory for Ms Catherine Clarke	General Manager, Specialist Acute Services, Acute Operations, HSE for Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance*
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance*
Dr Kevin Kelleher	Lay member	In attendance

*Parts of meeting and/or some voting not attended

In attendance (non-voting):
Professor Michael Barry (NCPE)

Secretariat:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS