HSE Drugs Group – March 2025 Minutes
Meeting 2025.03: Tuesday 11th March 2025, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the February 2025 meeting were considered and approved.

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

i. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from the February 2025 meeting have been progressed to the HSE Senior Leadership Team for consideration.

ii. The Group was provided with an update on the current Drugs Group membership vacancies.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Iptacopan (Fabhalta®) for paroxysmal nocturnal haemoglobinuria (PNH) (NCPE HTA ID: 24023)

The Drugs Group considered iptacopan (Fabhalta®) as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia. The Group discussed the dynamic PNH treatment landscape as evidenced by the number of pricing and reimbursement applications in this space (including biosimilar eculizumab). The Group acknowledged the need for additional PNH therapies that provide improved control for both treatment naïve and treatment experienced PNH patients. Iptacopan, an orphan drug and novel proximal complement inhibitor targeting Factor B, represents the first oral treatment option for PNH. Following consideration of the clinical and economic evidence, and the outputs of commercial negotiations, the Drugs Group unanimously recommended reimbursement of iptacopan under High Tech arrangements subject to the implementation of a managed access protocol.

ii. Crovalimab (Piasky®) for paroxysmal nocturnal haemoglobinuria (PNH) (HSE Pricing and Reimbursement Application Tracker ID: HSE100000 & NCPE HTA ID: 24027)

The Drugs Group considered crovalimab (Piasky®) as monotherapy for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH): In patients with haemolysis with clinical symptom(s) indicative of high disease activity & In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months. The Group acknowledged that crovalimab represented an additional treatment option for PNH patients. The clinical evidence was reviewed for both the treatment naïve and treatment experienced patient cohorts, with a number of trial limitations noted by the Group. The Group reviewed the economic evidence including the impact of the substantial commercial proposal which helped to address some of the uncertainties associated with crovalimab. Following deliberations, the Group unanimously recommended hospital pricing approval of crovalimab subject to the implementation of a managed access protocol.

iii. Olaparib (Lynparza®) for the adjuvant treatment of adults with germline *BRCA1/2*-mutations who have HER2-negative high risk early breast cancer (NCPE HTA ID: 22065)

The Drugs Group considered olaparib (Lynparza®) as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline *BRCA1/2*-mutations who have HER2-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. The Group acknowledged that patients with germline *BRCA* mutations (g*BRCA*m) are typically younger with a more aggressive disease phenotype. The Group noted that olaparib is the only targeted treatment option specifically for patients with g*BRCA*m, high-risk, HER2- negative early breast cancer in this disease setting. The Group reviewed the clinical and economic evidence as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC). The Group reviewed the impact of the commercial offer on the applicant's and NCPE's cost-effectiveness estimates, and acknowledged that olaparib versus 'watch and wait' [redacted] The Group unanimously recommended in favour of reimbursement of olaparib under High Tech arrangements for this indication.

iv. Olaparib (Lynparza®) for the maintenance treatment of adult patients with germline *BRCA1/2*-mutations who have metastatic adenocarcinoma of the pancreas (NCPE HTA ID: 24029)

The Drugs Group considered olaparib (Lynparza®) as monotherapy for the maintenance treatment of adult patients with germline *BRCA1/2*-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen. The Group acknowledged the aggressive nature of pancreatic cancer, which is associated with a very poor prognosis, emphasised by the close parallel between disease incidence and mortality. The Group noted that olaparib represented the first targeted maintenance therapy for patients with metastatic adenocarcinoma of the pancreas and a germline *BRCA* mutation after completing chemotherapy. The Group reviewed the clinical evidence from the POLO trial alongside the NCCP TRC recommendation, noting the progression free survival benefit but also the associated uncertainty in overall survival benefit. The Group noted the limitations of the pivotal trial but overall considered the clinical evidence encouraging in the context of the high unmet need. Having considered the strengths and limitations of the clinical evidence, the lack of therapeutic advances for this patient cohort, and the impact of the commercial proposal, the Drugs Group by majority recommended in favour of reimbursement of olaparib under High Tech arrangements for this indication.

5. AOB

Appendix 1: Members Present via videoconference

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	Assistant National Director, 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	Apologies received
Ms Carol Ivory for Position vacant	General Manager, Specialist Acute Services, Acute Operations, HSE for Strategy & Planning – Unscheduled Care (Assistant National Director)	Apologies received
Position vacant	Consultant in Inherited Metabolic Disorders	N/A
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance
Dr Kevin Kelleher	Lay member	Apologies received

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

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