HSE Drugs Group – July 2025 Minutes
Meeting 2025.07: Tuesday 8th July 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the June 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.

Following the June 2025 meeting, the Group were notified that two positive recommendations had now been progressed to the HSE Senior Leadership Team (SLT). Subsequent to conditional positive recommendations by the Drugs Group at this meeting, revised commercial offers satisfying the Drugs Group recommendations had been submitted by the respective applicants. HSE SLT consideration of these two applications was awaited:

- Durvalumab (Imfinzi®) in combination with gemcitabine and cisplatin for the first-line treatment of adults with unresectable or metastatic biliary tract cancer (NCPE HTA ID: 23009)
- Mavacamten (Camzyos®) for the treatment of symptomatic (New York Heart Association class II–III) obstructive hypertrophic cardiomyopathy in adult patients (NCPE HTA ID: 23028)

Selumetinib (Koselugo®) for the treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1 aged 3 years and above (NCPE HTA ID: 22032) was also considered by the Group at the June 2025 meeting. The Group were notified that CPU had subsequently met with the applicant to discuss the outputs of deliberations from the June 2025 Drugs Group meeting.

The pricing and reimbursement application for burosumab (Crysvita®) for the treatment of X-linked hypophosphataemia (XLH) in adult patients (NCPE HTA ID: 23005) had since been referred for consideration by the Rare Diseases Technology Review Committee (RDTRC).

3. Declaration of Interests / Nil Interest

One member declared a potential conflict of interest in relation to item iii. gilteritinib (Xospata®). One member declared a conflict of interest in relation to item iv. ocrelizumab (Ocrevus®). Both members abstained from deliberations and voting.

4. Medicines for Consideration

i. Ravulizumab (Ultomiris®) for the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uraemic syndrome (aHUS) (NCPE HTA ID: 20036)

The Drugs Group previously considered ravulizumab (Ultomiris®) in December 2022 for the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uraemic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab. The Group did not recommend reimbursement at this meeting. Following consideration by the HSE SLT, the Drugs Group recommendation was subsequently supported.

In response to the proposed written decision of the HSE SLT to refuse reimbursement of ravulizumab for this indication, the applicant (Alexion) submitted representations which were considered by the Drugs Group at their July 2025 meeting. The Group acknowledged the shift in the pricing landscape for a key comparator, eculizumab, with the reimbursement of a

biosimilar in the intervening period since last reviewed by the Group. Following consideration of the applicant's representations (including a revised commercial proposal), the Group unanimously recommended in favour of reimbursement, subject to the establishment of a managed access protocol.

ii. Ravulizumab (Ultomiris®) for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) (NCPE HTA ID: 19054)

The Drugs Group previously considered ravulizumab (Ultomiris®) in December 2022 for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) with haemolysis with clinical symptom(s) indicative of high disease activity or who are clinically stable after having been treated with eculizumab for at least the past 6 months. The Group did not recommend reimbursement at this meeting. Following consideration by the HSE SLT, the Drugs Group recommendation was subsequently supported.

In response to the proposed written decision of the HSE SLT to refuse reimbursement of ravulizumab for this indication, the applicant (Alexion) submitted representations which were considered by the Drugs Group at their July 2025 meeting. The Group acknowledged the shift in the pricing landscape for a key comparator, eculizumab, with the reimbursement of a biosimilar in the intervening period since last reviewed by the Group. The Group also considered the wider impact of the evolving PNH treatment landscape with a number of drugs having recently received positive reimbursement recommendations from the Group. Following consideration of the applicant's representations (including a revised commercial proposal), the Group unanimously recommended in favour of reimbursement, subject to the establishment of a managed access protocol.

iii. Gilteritinib (Xospata®) for the treatment of adult patients with relapsed or refractory acute myeloid leukaemia (NCPE HTA ID: 19043)

The Group considered gilteritinib (Xospata®) as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. The Drugs Group previously reviewed gilteritinib in October 2021 and February 2022 and agreed that a positive reimbursement recommendation could be supported on the basis of the [redacted].

The Group noted that this was the third time that gilteritinib was being reviewed for this indication. Additional evidence (including clinical evidence) had since been submitted which was considered to warrant further review by the Group. The Group noted the ongoing unmet need for additional therapies for this patient population. No new FLT3 targeted therapies had received marketing authorisation in this relapsed/refractory AML setting since last reviewed. Gilteritinib remains an orphan drug. The Group considered the clinical evidence, including real world evidence studies which broadly supported the pivotal trial's (ADMIRAL) outcomes regarding treatment duration, survival and transplant. A clinician representation was also considered by the Group in its deliberations. The Group reviewed the impact of the revised commercial proposal [redacted] on the cost-effectiveness and affordability. Following protracted deliberations weighing up the totality of information (including the revised commercial proposal and the additional information supporting this application), the Drugs Group by majority recommended in favour of restricted reimbursement. The Group recommended that in the event that patients re-initiate gilteritinib post-haematopoietic stem cell transplant (HSCT), gilteritinib should be restricted to patients who are minimal residual disease (MRD)-positive.

iv. Ocrelizumab (Ocrevus®) subcutaneous presentation for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) and for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) (HSE Pricing and Reimbursement Application tracker ID: HSE100019, NCPE HTA ID: 25015)

The Group considered a pricing and reimbursement application for ocrelizumab (Ocrevus®) 920 mg solution for injection (for subcutaneous administration) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features and the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity. The Group noted that subcutaneous administration of ocrelizumab is a less invasive, more convenient treatment option for patients which also represents an opportunity to create time and resource efficiencies within the health service. Following review of the clinical and economic evidence, including the proposed commercial offer [redacted] the Group unanimously supported reimbursement of the subcutaneous ocrelizumab presentation under the National Drug Management System (NDMS).

v. Voclosporin (Lupkynis®) for the treatment of adult patients with lupus nephritis (NCPE HTA ID: 23003)

The Drugs Group reviewed voclosporin (Lupkynis®) in combination with mycophenolate mofetil (MMF) for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN). The Group acknowledged the need for new treatment options for lupus nephritis patients. Voclosporin, which is administered orally, represents the first calcineurin inhibitor licensed specifically for LN. The Group discussed the clinical evidence, noting that the addition of voclosporin to standard of care (MMF plus glucocorticoids) improved renal response rates. The Group reviewed the impact of the substantial commercial proposal, noting [redacted] Following deliberation on the available evidence and having considered the commercial proposal, the Group unanimously recommended in favour of reimbursement of voclosporin under High Tech arrangements.

vi. Aztreonam + avibactam (Emblaveo®) for the antimicrobial treatment of adult patients (NCPE HTA ID: 24037)

The Drugs Group considered aztreonam + avibactam (Emblaveo®) for the treatment of the following infections in adult patients: complicated intra-abdominal infection (cIAI), hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), complicated urinary tract infection (cUTI), including pyelonephritis. Emblaveo® is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options. The Drugs Group unanimously recommended in favour of hospital pricing approval of Emblaveo®. In making its recommendation, the Group acknowledged the continued need for additional antimicrobial therapies in the context of antimicrobial resistance challenges. Whilst Emblaveo® represents a relatively expensive antimicrobial treatment, the budget impact is anticipated to be modest (factoring in the commercial proposal) and utilisation will be in accordance with appropriate hospital antimicrobial stewardship.

5. AOB

No AOB raised.

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	Apologies received
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)	In attendance*
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	In attendance

*Parts of meeting and/or some voting not attended

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

Secretariat:
Linda Fitzharris, Head of Corporate Pharmaceutical Unit & Pharmacy Function, PCRS
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Senior Pharmacist, CPU PCRS