HSE Drugs Group – September 2025 Minutes
Meeting 2025.09: Tuesday 9th September 2025, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the August 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 progressed to the HSE Senior Leadership Team for consideration had been supported.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Isavuconazole (Cresemba®) for patients from 1 year of age to less than 18 years for the treatment of invasive aspergillosis, and mucormycosis in patients for whom amphotericin B is inappropriate (HSE Pricing and Reimbursement Application tracker ID: HSE100027, NCPE HTA ID: 25016)

The Drugs Group considered isavuconazole (Cresemba®) for patients from 1 year of age to less than 18 years for the treatment of invasive aspergillosis, and mucormycosis in patients for whom amphotericin B is inappropriate. The Group acknowledged that isavuconazole (an orphan medicine) offered an alternative treatment option for these rare, but life-threatening, fungal infections. Isavuconazole does not routinely require therapeutic drug monitoring and has a more predictable pharmacokinetic profile than voriconazole. Notwithstanding the high treatment cost of isavuconazole, following consideration of the challenges in treating these invasive fungal infections, the available clinical and cost-effectiveness evidence, the budgetary impact, and the impact of the commercial proposal, the Drugs Group, by majority, recommended in favour of hospital pricing approval / reimbursement under High Tech arrangements of isavuconazole. In making its recommendation, the Group acknowledged the continued need for additional antimicrobial therapies in the context of antimicrobial resistance challenges.

ii. Epcoritamab (Tepkinly®) as monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy (NCPE HTA ID: 24010)

The Drugs Group considered epcoritamab (Tepkinly®) as monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. The Group acknowledged the poor prognosis for this patient cohort and the need for additional therapies to improve treatment outcomes, resistance to existing therapies and safety profiles. The Group noted that epcoritamab represented a novel, chemotherapy-free, subcutaneous, monotherapy option for patients. The unmet need was further supported by advice from the NCCP TRC. The Group discussed the inherent challenges in interpreting data from the early phase I/II, open-label, single-arm EPCORE NHL-1 trial and

the lack of direct comparative evidence versus available therapies. Having considered the totality of clinical and economic evidence, and the impact of the commercial proposal versus available therapies, the Drugs Group unanimously recommended in favour of reimbursement of epcoritamab for this indication under the Oncology Drug Management System (ODMS).

iii. Brexucabtagene autoleucel (Tecartus®) for the treatment of adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL) (NCPE HTA ID: 23045)

The Drugs Group considered brexucabtagene autoleucel (Tecartus®) for the treatment of adult patients 26 years of age and above with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukaemia (ALL). The Group acknowledged the poor prognosis for adult B-cell ALL patients and that brexucabtagene autoleucel (an orphan medicine) addresses an unmet medical need in patients aged 26 years and above for which CAR-T therapy is currently unavailable in Ireland. The Group noted that tisagenlecleucel (Kymriah®) was reimbursed under the ODMS in July 2021 for the treatment of paediatric and young adult patients up to 25 years of age with r/r B-cell ALL. In reviewing the clinical evidence, the Group noted the single-arm, open-label nature of the pivotal phase 1/2 trial and the limitations of same but acknowledged the durable response rates observed and the overall survival data available at the 5 year update of the ZUMA-3 trial. Advice from the NCCP TRC was also considered by the Group in its deliberations. Following consideration of the impact of the commercial proposal on cost-effectiveness and budget impact estimates, the Group unanimously recommended in favour of reimbursement of brexucabtagene autoleucel under the Oncology Drug Management System (ODMS) for this indication.

iv. Talquetamab (Talvey®) as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy (NCPE HTA ID: 23057)

The Drugs Group considered talquetamab (Talvey®) as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (MM), who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. The Group discussed the evolving treatment landscape for MM and acknowledged the significant investment by the State in funding MM therapies over recent years. Teclistamab (a bispecific T cell engager therapy) and ciltacabtagene autoleucel (a CAR-T therapy) recently received funding approval in Ireland for this cohort of triple-class refractory MM patients. Nonetheless, the Group recognised that talquetamab (an orphan medicine and the only licensed GPRC5D-targeted therapy for MM) represented an alternative bispecific T cell engager treatment option for patients. The Group in its deliberations reviewed advice from the NCCP TRC as well as a patient organisation submission from Multiple Myeloma Ireland. The Group reviewed the available clinical evidence from the pivotal MonumenTAL-1 trial, noting the inherent limitations of the phase I/II, single-arm, open-label design. Taking into consideration the benefits and uncertainties in the clinical and pharmacoeconomic evidence (incorporating the commercial proposal), against the backdrop of the evolving MM treatment landscape, the Drugs Group unanimously recommended in favour of reimbursement of talquetamab for this indication under the Oncology Drug Management System (ODMS).

5. AOB

i. Following deliberation of all of the medicines for consideration, the Group raised a common theme seen amongst the medicines discussed throughout the meeting. The Group reiterated the inherent challenges, limitations and uncertainties in interpreting data from early phase, open-label, single arm trials. The Group noted the increasing prevalence of such trials. The difficulties and discomfort faced by the Group in making recommendations (of very substantial budgetary impact to the HSE) based on this early phase, non-comparative clinical trial data was discussed.

ii. The Chair and Drugs Group members acknowledged the imminent retirement of Dr. Philip Crowley. Dr Crowley's tenure as a Drugs Group member spanned many years and his considered input, contributions and vast experience within the Drugs Group will be greatly missed. A suitable replacement will now be sought to fill the vacated position.

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)	Apologies received
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
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance
Dr Kevin Kelleher	Lay member	In attendance
Professor Atif Awan	Consultant Paediatric Nephrologist & Clinical Lead - National Rare Diseases Office	In attendance

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

Secretariat:
Linda Fitzharris, Head of Corporate Pharmacy Unit and Pharmacy Function, PCRS
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Aoife O'Reilly, Chief II Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Senior Pharmacist, CPU PCRS