HSE Drugs Group – June 2025 Minutes
Meeting 2025.06: Tuesday 10th June 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the May 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 at the May 2025 meeting had been supported.

ii. Axicabtagene ciloleucel (Yescarta®) for the treatment of adult patients with diffuse large B-cell lymphoma and high-grade B-cell lymphoma that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy (NCPE HTA ID: 22066) was considered by the Group at the May 2025 meeting. The Group were notified that CPU had subsequently met with the applicant to discuss the outputs of deliberations from the May 2025 meeting.

3. Declaration of Interests / Nil Interest

One member declared a potential interest in relation to item i. burosumab (Crysvita®) for XLH in adult patients. This member abstained from deliberations and voting.

4. Medicines for Consideration

i. Burosumab (Crysvita®) for the treatment of X-linked hypophosphataemia (XLH) in adult patients (NCPE HTA ID: 23005)

The Drugs Group considered burosumab (Crysvita®) for X-linked hypophosphataemia (XLH) in adult patients. The Group noted that the applicant was seeking hospital pricing approval for a subpopulation of the licensed indication (i.e. for the treatment of adults with XLH, who have persistent symptoms despite conventional therapies or who are intolerant of conventional therapies). The Group acknowledged that burosumab (Crysvita®) for the treatment of XLH with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons received HSE hospital pricing approval in May 2021. The Group considered the unmet need, the clinical and economic evidence, alongside the output of commercial negotiations. The Group were unable to progress a recommendation that was supportive of reimbursement on the basis of the totality of available evidence. As the application was for a medicine for the management of a rare disease, further patient and clinician engagement input via the HSE Rare Diseases Technology Review Committee (RDTRC) would be sought. The Group committed to reviewing the output of the RDTRC at the earliest opportunity and would consider a reimbursement recommendation at that time.

ii. 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)

The Drugs Group considered durvalumab (Imfinzi®) in combination with gemcitabine and cisplatin for the first-line treatment of adults with unresectable or metastatic biliary tract cancer (BTC). The Group acknowledged the highly aggressive nature and poor patient prognosis associated with BTC. Median overall survival for patients who receive chemotherapy (current standard of care in

Ireland) is approximately 1 year. Durvalumab in combination with chemotherapy represents the first immunotherapy based regimen for BTC to seek reimbursement in Ireland. In reviewing the clinical evidence, the Group noted the modest overall survival (OS) gain associated with the durvalumab + chemotherapy arm versus the chemotherapy arm in the pivotal TOPAZ-1 trial. The Group also noted the OS rate for the durvalumab arm was greater than double that for the comparator arm at 36 months. The Group in its deliberations reviewed advice from the NCCP TRC as well as a patient organisation submission from AMMF – The Cholangiocarcinoma Charity. The Group considered that the addition of durvalumab to gemcitabine and cisplatin represented a substantially higher treatment cost relative to chemotherapy. Taking into consideration the clinical evidence and uncertainties associated with the cost-effectiveness analysis, coupled with a large budget impact, the Drugs Group by majority agreed that it could support a positive reimbursement recommendation subject to [redacted].

iii. Selumetinib (Koselugo®) for the treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1 (NCPE HTA ID: 22032)

The Group considered selumetinib (Koselugo®) as monotherapy for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above. The Group acknowledged that neurofibromatosis type 1 is a rare and progressive disease. Selumetinib, an orphan medicine, represents the first licensed medicine for this paediatric patient cohort. The Drugs Group considered a comprehensive patient organisation submission from the Neurofibromatosis Association of Ireland in its deliberations. The Group reviewed evidence from the SPRINT trial, a phase II, open-label, single-arm study. The magnitude of clinical benefit of selumetinib was associated with considerable uncertainty given the single-arm nature of the study and the lack of direct comparative evidence. The Group considered the limitations and uncertainties associated with the pharmacoeconomic evidence. The Group noted the wide variance between the applicant and NCPE's cost effectiveness estimates, ranging from €82,373/QALY (applicant base case) to €380,985/QALY (NCPE adjusted base case) for selumetinib versus best supportive care at list price. The Drugs Group agreed that it could not support reimbursement of selumetinib (Koselugo®) on the basis of the available information and commercial proposal. The Drugs Group specifically requested that the HSE Corporate Pharmaceutical Unit (CPU) re-engage with Alexion on [redacted]

iv. Mavacamten (Camzyos®) for the treatment of symptomatic obstructive hypertrophic cardiomyopathy in adult patients (NCPE HTA ID: 23028)

The Group considered mavacamten (Camzyos®) for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients. Mavacamten is the first medicine to be licensed specifically for the treatment of oHCM. The Group reviewed the clinical and economic evidence in detail as well as the output of commercial negotiations. In the pivotal EXPLORER-HCM trial, compared with placebo,

mavacamten treatment resulted in significantly greater proportions of patients achieving the composite primary outcome, which assessed exercise capacity (pVO_2) and symptomatic burden (NYHA class). At list price, mavacamten + beta-blocker (BB) / calcium channel blocker (CCB) was not considered cost-effective versus BB/CCB monotherapy from either the applicant's (€66,330/QALY) or NCPE's perspective (€133,164/QALY). The Group acknowledged that mavacamten could provide a benefit for a select cohort of patients but considered the relative long-term effectiveness of mavacamten vs Standard of Care (SoC) to be subject to uncertainty. The lack of cardiovascular outcome data (such as reduction in hospitalisations or mortality) was considered to be a significant uncertainty by the Group. Taking into consideration the uncertainties in the clinical evidence, the Group by majority agreed that it could support reimbursement subject to [redacted] coupled with the establishment of a managed access protocol.

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	Apologies received
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)	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	Apologies received
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