HSE Drugs Group – August 2025 Minutes
Meeting 2025.08: Tuesday 12th August 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

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

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

i. The Chair welcomed Professor Atif Awan to the HSE Drugs Group as a newly appointed member.

ii. 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. Ribociclib (Kisqali®) for the adjuvant treatment of patients with hormone receptor positive, human epidermal growth factor receptor 2-negative early breast cancer at high risk of recurrence (HSE Pricing and Reimbursement Application tracker ID: HSE100007, NCPE HTA ID: 24045)

The Drugs Group considered ribociclib (Kisqali®) in combination with an aromatase inhibitor for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence. In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. The Group acknowledged that ribociclib addressed an unmet need for a node-negative cohort of early breast cancer patients (in line with the inclusion criteria in the NATALEE trial). The Group also recognised that ribociclib represents an alternative CDK 4/6 inhibitor treatment option to abemaciclib with a maximum treatment duration of 3 years. The differences in the adverse event profile of ribociclib versus abemaciclib was considered to offer relevant patients additional choice. Advice from the NCCP TRC was also considered by the Group in their deliberations. Following consideration of the unmet need, the available clinical and cost-effectiveness evidence and the budgetary impact (incorporating the commercial proposal), the Group by majority recommended in favour of reimbursement of ribociclib under High Tech arrangements for this indication.

ii. Ivosidenib (Tibsovo®) for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation (NCPE HTA ID: 23016)

The Drugs Group considered ivosidenib (Tibsovo®) as monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated with at least one prior line of systemic therapy. The Group acknowledged the aggressive nature and poor prognosis associated with cholangiocarcinoma (CCA). The Group acknowledged that ivosidenib (an orphan medicine) represents the only authorised targeted therapy for the treatment of any solid tumour bearing an IDH1 mutation in CCA. The Group acknowledged the progression-free survival and overall survival benefit for ivosidenib versus placebo in the pivotal ClarIDHy trial as well as [redacted]

[redacted] The Drugs Group considered a patient organisation submission from AMMF, The Cholangiocarcinoma Charity, alongside advice from the NCCP TRC in its deliberations. Following consideration of the available evidence in the context of the significant unmet need for targeted treatment options for this patient cohort, and having considered the impact of the commercial proposal on cost-effectiveness estimates, the Group unanimously recommended in favour of reimbursement of ivosidenib under High Tech arrangements.

iii. Ciltacabtagene autoleucel (Carvykti®) for the treatment of adult patients with relapsed or refractory multiple myeloma (NCPE HTA ID: 22021)

The Drugs Group reviewed ciltacabtagene autoleucel (Carvykti®) for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM), 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. The Group noted that median overall survival in multiple myeloma patients who have received ≥3 prior lines of therapy and are refractory to both an immunomodulatory agent and a proteasome inhibitor is approximately 13 months. The reported overall response rate (ORR) for approved therapies for heavily pre-treated and refractory patients is approximately 30%. The Group acknowledged the need for additional therapies for this triple-class exposed RRMM patient cohort. Ciltacabtagene autoleucel (an orphan medicine) represents the first CAR-T therapy to be considered for reimbursement in this patient population. In reviewing the clinical evidence, the Group noted the impressive data from the pivotal CARTITUDE-1 trial, notwithstanding the associated uncertainties in interpreting data from a single-arm, open-label trial. The ORR, based on the final data cut (median follow-up: 27.7 months), was 97.9% in the mITT population. Median overall survival was 60.7 months at a median treatment follow-up of 61.3 months (considering data from the CARTinue study). A patient organisation submission from Multiple Myeloma Ireland was reviewed by the Group in addition to advice from the NCCP TRC. The Group noted the impact of the commercial proposal on cost-effectiveness estimates. Following deliberations, the Group by majority recommended in favour of ciltacabtagene autoleucel reimbursement under the Oncology Drug Management System (ODMS).

iv. Nivolumab (Opdivo®) in combination with ipilimumab (Yervoy®) for the first-line treatment of adult patients with unresectable or metastatic mismatch repair deficient or microsatellite instability-high colorectal cancer (HSE Pricing and Reimbursement Application tracker ID: HSE100014, NCPE HTA ID: 25003)

The Drugs Group considered nivolumab (Opdivo®) in combination with ipilimumab (Yervoy®) for the first-line treatment of adult patients with unresectable or metastatic mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) colorectal cancer. The Group recognised that dMMR/ MSI-H colorectal cancer (CRC) can be associated with a worse prognosis than microsatellite stable disease in the metastatic setting. The Group discussed the clinical evidence from the CheckMate 8HW pivotal study, noting a statistically significant improvement in progression-free survival for nivolumab + ipilimumab compared with standard of care chemotherapy. The Group noted that nivolumab + ipilimumab offered a combination treatment option, which may be used in younger, fitter patients as an alternative to pembrolizumab. The Group also considered advice from the NCCP TRC. The Group reviewed the impact of the commercial proposal, [redacted] The Group also noted that [redacted] Following consideration of the clinical and cost-effectiveness evidence, the Drugs Group unanimously recommended in favour of reimbursement.

5. **AOB**
No AOB raised.

Appendix 1: Members Present via videoconference

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	Apologies received
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 (Acting Chair)
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	Apologies received
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
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	Apologies received
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:
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Senior Pharmacist, CPU PCRS