HSE Drugs Group – April 2025 Minutes
Meeting 2025.04: Tuesday 8th April 2025, 14.00 – 17.00
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the March 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 from the March 2025 meeting had been supported.

ii. The Chair welcomed Ms. Linda Fitzharris to her inaugural meeting of the HSE Drugs Group as the new Head of the Corporate Pharmaceutical Unit. The Group noted that Ms. Fitzharris also retained her prior role as Head of Pharmacy Function within the HSE Primary Care Reimbursement Service.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Carfilzomib (Kyprolis®) in combination with daratumumab and dexamethasone for the treatment of multiple myeloma (NCPE HTA ID: 20054)

The Drugs Group considered carfilzomib (Kyprolis®) in combination with daratumumab and dexamethasone (car/dar/dex) for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. The Drugs Group discussed the rapidly evolving MM treatment landscape and acknowledged that car+dar+dex (a lenalidomide-sparing regimen) represents an additional treatment option for patients. The Group noted that carfilzomib and daratumumab held orphan drug designation status. The Group reviewed the clinical evidence, acknowledging the limitations of the CANDOR study. The Group discussed the uncertainty as to whether the PFS benefit observed in the trial will translate into an OS benefit given the CANDOR trial did not demonstrate a statistically significant improvement in OS for car/dar/dex v car/dex. The Drugs Group considered a patient organisation submission from Multiple Myeloma Ireland in its deliberations. Advice from the NCCP TRC was also reviewed. In the absence of direct head-to-head evidence, indirect treatment comparisons were conducted to inform relative treatment effects of additional model comparators (daratumumab + bortezomib + dexamethasone (dar+bor+dex) and pomalidomide + bortezomib + dexamethasone (pom+bor+dex). Despite consideration of the commercial proposal, cost effectiveness estimates remained far in excess of conventional willingness to pay thresholds regardless of comparator or subpopulation from either the applicant or NCPE's perspective. The Group considered that car+dar+dex did not represent a cost effective, optimum use of limited HSE resources. Following protracted deliberations, based on the totality of currently available evidence, the Drugs Group by majority recommended against reimbursement of car/dar/dex for this indication.

ii. Tisagenlecleucel (Kymriah®) for the treatment of relapsed or refractory follicular lymphoma (NCPE HTA ID: 22044)

The Drugs Group considered tisagenlecleucel (Kymriah®) for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. The Group acknowledged an unmet need in FL patients with frequent relapses, where therapies generally result in modest complete response rates that are not durable, thus necessitating further treatments with associated toxicities and risk of histological transformation. Tisagenlecleucel, an autologous, single-dose, immunocellular, orphan cancer therapy, represents the first CAR-T

treatment for FL to be considered by the Group. In reviewing the clinical evidence, the Group noted the immaturity of the overall survival data but acknowledged the durable complete response rates observed and the magnitude of the median progression–free survival results available at the 4-year update of the ELARA trial. The Group also reviewed advice from the NCCP TRC. The Group discussed the pharmacoeconomic evidence and the improvement in cost effectiveness considering the commercial proposal. Following deliberations, the Group by majority recommended in favour of tisagenlecleucel reimbursement under the Oncology Drug Management System (ODMS), having weighed up the unmet need, clinical and pharmacoeconomic evidence, notwithstanding the substantial budgetary impact.

iii. Trastuzumab deruxtecan (Enhertu®) for the treatment of unresectable or metastatic HER2-low breast cancer (NCPE HTA ID: 23011)

The Group considered trastuzumab deruxtecan (Enhertu®) as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. The Group discussed the recent reclassification of HER2 status as a spectrum of HER2 expression levels rather than the traditional binary positive/negative approach. The Group noted that trastuzumab deruxtecan represents the first specifically approved HER2-low treatment for this breast cancer cohort. The Group acknowledged the progression-free survival and overall survival benefit for trastuzumab deruxtecan versus treatment of physician's choice in the pivotal DESTINY-Breast04 trial. The Group also considered advice from the NCCP TRC. The Group reviewed the impact of the commercial proposal on the pharmacoeconomic evidence, noting the proposed [redacted] Following consideration of the clinical and cost effectiveness evidence, the Drugs Group, by majority, recommended in favour of reimbursement of trastuzumab deruxtecan for this indication under the Oncology Drug Management System (ODMS).

iv. Lutetium (^{177}Lu) vipivotide tetraxetan (Pluvicto®) for PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) (NCPE HTA ID: 23002)

The Drugs Group considered lutetium (^{177}Lu) vipivotide tetraxetan (Pluvicto®) in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition for the treatment of adult patients with progressive prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane-based chemotherapy. The Group acknowledged the unmet need for additional treatment options for this patient cohort given the limited available therapies. Pluvicto®, a PSMA-targeted radioligand therapy, offers an alternative treatment option to chemotherapy in this disease setting. In reviewing the clinical evidence, the Group noted several limitations including the high withdrawal rates in the pivotal VISION trial, its open-label design and the exclusion of cabazitaxel from standard of care treatment. From the available clinical evidence, Pluvicto® has not demonstrated a clear overall survival benefit versus cabazitaxel. The Drugs Group considered a patient interest group submission from Men Against Cancer, advice from the NCCP TRC and two additional clinician representations (clinicians submitted formal declarations stating no conflict of interest). The Group noted cost effectiveness estimates far exceeded conventional willingness to pay thresholds from both the applicant and NCPE perspectives at both list and [redacted]. Pluvicto® is also associated with high and uncertain budgetary impact estimates. Following extensive deliberations, the Drugs Group unanimously recommended against reimbursement of Pluvicto®, under the Oncology Drug Management System (ODMS) for this indication having agreed it did not represent an optimum use of limited HSE resources.

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)	Apologies received
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	Apologies received
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	In attendance
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

In attendance (non-voting):
Dr Laura McCullagh (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