HSE Drugs Group – April 2024 Minutes
Meeting 2024.04: Tuesday 9th April 2024, 14.00 – 16.30
Via videoconference

1. **Draft Minutes for Consideration**
   The minutes of the March 2024 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. The HSE Executive Management Team (EMT) supported reimbursement of the three medicines with positive recommendations from the February 2024 meeting.

   The recommendations from the March 2024 meeting were under consideration by the HSE EMT. The Group were also notified that a positive recommendation for Avacopan (Tavneos®), in combination with a Rituximab or Cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) had also been progressed to the HSE EMT. Following a conditional positive recommendation by the Drugs Group in February 2024, a revised commercial offer satisfying the qualified positive recommendation had since been submitted by the applicant.

3. **Declaration of Interests / Nil Interest**
   None declared

4. **Medicines for Consideration**

   i. **Daratumumab (Darzalex®) in combination with Lenalidomide and Dexamethasone for transplant ineligible newly diagnosed multiple myeloma (NCPE HTA ID: 22039)**

   The Group considered Daratumumab (Darzalex®) in combination with Lenalidomide and Dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. The Group previously considered Daratumumab for this indication at the February 2024 meeting. Following protracted deliberations at this meeting, the Group were unable to make a recommendation and requested additional information from the NCPE to inform further deliberations.

   At their April 2024 meeting, the Group reviewed and discussed the totality of clinical and economic evidence in detail. This included the additional NCPE analyses as requested by the Group and the output of further commercial negotiations. The Group also noted that Lenalidomide had recently been designated an interchangeable medicine by the Health Products Regulatory Authority (HPRA) (March 2024). The potential impact of a reduced Lenalidomide price on cost-effectiveness estimates was reviewed, with the Group noting Lenalidomide is anticipated to be reference priced in the near future.The Group acknowledged the unmet need for a Daratumumab regimen in the newly diagnosed, transplant ineligible patient cohort, the significant progression-free survival (PFS) treatment benefit demonstrated by Daratumumab in combination with Lenalidomide and Dexamethasone, and the promising but immature overall survival (OS) results in the pivotal MAIA trial. Following lengthy deliberations, the Drugs Group, by a single majority vote, recommended in favour of reimbursement. The Group noted this majority positive recommendation was against the backdrop of a very substantial and challenging budget impact for the HSE.

ii. Dapagliflozin (Forxiga®) for the treatment of Chronic Kidney Disease (CKD) (NCPE HTA ID: 22040)

The Drugs Group considered Dapagliflozin (Forxiga®) for the treatment of chronic kidney disease (CKD) in adults. The Group acknowledged that the treatment landscape of CKD has evolved considerably in recent years. International guidelines for the management of CKD recommend control of hypertension, CV risk management, the use of a renin– angiotensin - aldosterone system (RAAS) blocker (angiotensin-converting–enzyme [ACE] inhibitor or angiotensin-receptor blocker [ARB]), glucose lowering therapies where glycaemic control is necessary, and more recently a sodium–glucose cotransporter 2 (SGLT2) inhibitor. The evidence from the pivotal DAPA-CKD trial supporting the marketing authorisation for Dapagliflozin in patients with CKD was reviewed by the Group. The clinical benefit was noted, with Dapagliflozin demonstrating statistically significant superiority to placebo in preventing the primary composite endpoint. The Drugs Group unanimously recommended reimbursement of Dapagliflozin for the treatment of CKD, on the basis of the strength of the clinical evidence presented to the Group, and the recent evolution of the role of SGLT2 inhibitors in the CKD treatment pathway, as recognised in international guidelines.

iii. Pembrolizumab for neoadjuvant and adjuvant treatment of triple negative breast cancer (TNBC) (NCPE HTA ID: 22027)

The Drugs Group considered Pembrolizumab (Keytruda®) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, for the treatment of adults with locally advanced, or early-stage triple-negative breast cancer at high risk of recurrence. The Group acknowledged that TNBC is associated with higher tumor grade at diagnosis, a higher risk of distant disease recurrence, and poor clinical outcomes, with most relapses occurring within the first 3 years after surgery. The Group reviewed the available clinical and economic evidence, including the National Cancer Control Programme Technology Review Committee (NCCP TRC) recommendation. The impact of the revised commercial offer now rendered Pembrolizumab for this indication [redacted] The Group noted that additional cost offsets are also anticipated [redacted]. Following lengthy deliberation, the Group by majority recommended in favour of reimbursement of Pembrolizumab under the Oncology Drug Management System (ODMS) for this indication, on the basis of the clinical and cost effectiveness evidence, notwithstanding the exceptionally large budget impact.

iv. Chlormethine gel for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) (NCPE HTA ID: 23049)

The Drugs Group considered Chlormethine (Ledaga®) for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients. The Group acknowledged that CTCL represents a rare and heterogeneous group of lymphoproliferative diseases characterised by infiltration of the skin by malignant T-cells, with MF-type CTCL subtype accounting for approximately 60% of cases. Treatment is guided by the stage of the disease and ranges from skin directed therapies (SDT) (including topical agents, phototherapy and radiotherapy) for early-disease to systemic treatments (including biologics, chemotherapy) for more advanced disease, which may be combined with SDT. Topical chemotherapy, including topical Chlormethine, is recommended as a SDT option in international guidelines. The Group reviewed the totality of clinical and economic evidence for Chlormethine gel (an orphan medicine) as well as the applicant's commercial proposal of a

[redacted] The Drugs Group unanimously recommended reimbursement of Chlormethine (Ledaga®) acknowledging the unmet need in this patient cohort and the [redacted]

5. AOB

i. Clare Mac Gabhann notified the Group of their imminent retirement. A suitable replacement was being sought to fill their position.

Appendix 1: Members Present on Microsoft Teams

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)	Apologies received
Ms Patricia Heckmann for Professor Risteárd Ó Laoide	Chief Pharmacist, 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
Clare Mac Gabhann	Director of Nursing and Midwifery (Prescribing)	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	Apologies received
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Catherine Clarke	Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

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

Secretariat:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS