HSE Drugs Group – August 2023 Minutes

Meeting 2023.07: Tuesday 22nd August 2023, 14.00 – 16.30

Via videoconference

1. Draft Minutes for Consideration

The minutes of the June 2023 meeting were considered and approved.

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

i. The Chair welcomed Catherine Clarke to the HSE Drugs Group as a newly appointed committee member.

ii. The Chair welcomed officials from the Department of Health who are in a process of reviewing recommendations arising from the Mazars 2020 Report (*'Review of the Governance Arrangements and the Resources currently in place to support the Health Service Executive reimbursement and pricing decision-making process'*). Department officials were advised that a shortened Drugs Group medicines agenda was prepared in order have the necessary time in the scheduled meeting to facilitate introductions and a Q&A exchange (as required) between Drugs Group members and Department officials.

iii. The Secretariat informed the Drugs Group that The Rare Diseases Medicinal Products Technology Review Committee (RDTRC) have issued a statement in relation to the medicine Darvadstrocel (Alofisel®) and are currently drafting a clinical guideline, which are to be brought to the Drugs Group for consideration at a future meeting.

iv. The Drugs Group were also informed that a previous agenda item, Pegvaliase (Palynziq®) has been referred to the RDTRC for further input and advice.

v. An update on items previously considered by the Drugs Group was provided, including the number of items that had been considered in the first six meetings of the Drugs Group in 2023 and EMT approvals following positive Drugs Group recommendations from the May and June meetings. The Drugs Group were also notified that (as of the date of the meeting) 21 new medicines and new uses of existing medicines have been approved for reimbursement/hospital pricing approval by the HSE.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. 23017 Sacituzumab govitecan for the treatment of metastatic triple-negative breast cancer (mTNBC) (NCPE HTA ID: 22007)

The Drugs Group considered Sacituzumab govitecan (Trodelvy®) as monotherapy for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease.

The Group reviewed the clinical and economic evidence in detail, the outputs of commercial negotiations, as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC).

The Drugs Group noted that mTNBC is associated with a poor prognosis. The main clinical efficacy results derive from one pivotal study (ASCENT) where a survival benefit was observed for patients

treated with Sacituzumab Govitecan compared with patients on Treatment of Physician's Choice (TPC), to include one of the following single-agent regimens: eribulin, capecitabine, gemcitabine or vinorelbine, determined before randomisation. Median OS was 11.8 months vs 6.9 months (HR 0.51, 95% CI 0.42, 0.63; p<0.0001) in the intention to treat (ITT) population, compared with TPC.

Sacituzumab govitecan is associated with very high drug acquisition costs. Within the economic analysis the resulting ICERs at list price ranged from €129,356/QALY (Applicant base case, Sacituzumab govitecan vs TPC) to €216,138/QALY (NCPE adjusted base case, Sacituzumab govitecan vs TPC), which far exceed conventional willingness to pay thresholds. The impact of commercial offer ( ) submitted by the applicant company was considered by the Group to be of insufficient magnitude to support a positive recommendation. On the basis of the supporting clinical and cost-effectiveness evidence presented the Drugs Group were in favour of supporting reimbursement only if the commercial offer was revised to be a . The Group considered such an offering could be supported due to the high level of unmet need for efficacious therapies in this setting.

ii. 23018 Romosozumab for osteoporosis (NCPE HTA ID: 21016)

The Drugs Group considered Romosozumab (Evenity®) for the treatment of severe osteoporosis in women who are postmenopausal and are at high risk of fracture. The population considered was women who are postmenopausal, with severe osteoporosis, who have experienced a major osteoporotic fracture (MOF) within the previous 24 months and who are at imminent risk of another fragility fracture (a subpopulation of product licence).

The Group reviewed the clinical and economic evidence in detail as well as the Patient Organisation submission of evidence received during the HTA process for Romosozumab (Evenity®).

The Group acknowledged that osteoporotic fractures cause considerable morbidity and mortality and that their incidence is increasing due to an increase in the ageing population in Ireland. On the basis of the totality of the evidence presented the Drugs Group unanimously recommended in favour of reimbursement of Romosozumab (Evenity®) subject to and subject to there being a HSE Managed Access Protocol put in place to support prescribing that is restricted to the eligible population identified in the assessment.

iii. 23019 Dostarlimab for recurrent or advanced endometrial cancer (dMMR/MSI-H subtype) (NCPE HTA ID: 21045)

The Drugs Group considered Dostarlimab (Jemperli®) indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

The Group reviewed the clinical and economic evidence in detail as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC).

The Group acknowledged that Dostarlimab is the first treatment and immunotherapy licensed for dMMR/MSI-H recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen. The Group noted that there was uncertainty with regards to the clinical efficacy of Dostarlimab owing to the fact that the pivotal trial supporting marketing authorisation (GARNET) was a phase I, single-arm trial and that the lack of a comparator arm in GARNET makes interpretation of relative benefits versus current standard of care challenging. The Group also noted that there is uncertainty about long-term survival given the immaturity of data from the GARNET study.

On the basis of the high level of uncertainty in both the clinical and cost effectiveness evidence presented the Drugs Group unanimously recommended in favour of reimbursement of Dostarlimab (Jemperli®) only [redacted] The current commercial offer was not considered to adequately address the level of uncertainty.

5. AOB

The Chair facilitated a Q&A exchange between Department of Health officials and members of the Drugs Group & Secretariat.

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)	In attendance
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)	Apologies received
Clare Mac Gabhann	Director of Nursing and Midwifery (Prescribing)	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	Position vacant
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	In attendance
Dr Anne Dee	Specialist in Public Health Medicine	Apologies received
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	Apologies received

In attendance (non-voting):
Professor Michael Barry (NCPE)
Conor Gallagher (Department of Health)
David Cullinane (Department of Health)
Michael Holton (Department of Health)
Carl O'Gorman (Department of Health)

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
James Kee, Chief II Pharmacist, CPU PCRS
Lisa Kenny, Senior Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS