HSE Drugs Group – December 2021 Minutes

Meeting 2021.10: Tuesday 14th December 2021, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the November 2021 meeting were considered and approved.

2. Confidentiality forms

It had previously been agreed that all members (including public servants) would sign confidentiality forms (once off action).

3. Matters arising / Update on Medicines considered at previous meetings

An update on items previously considered by the Drugs Group was provided.

Pembrolizumab (Keytruda®) as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a CPS≥1, received a qualified positive recommendation from the Drugs Group in October 2021. The applicant (MSD) submitted a revised commercial offer that met the conditions required by the Drugs Group to progress a positive recommendation. The HSE EMT subsequently approved Pembrolizumab for this indication.

Esketamine (Spravato®) in combination with a SSRI or SNRI, for adults with treatment-resistant major depressive disorder, who have not responded to at least 2 different treatments with antidepressants in the current moderate to severe depressive episode, received a qualified positive recommendation from the Drugs Group in November 2021. The applicant (Janssen) submitted a revised commercial offer that met the conditions required by the Drugs Group to progress a positive recommendation. The HSE EMT subsequently approved Esketamine for this indication.

Following a positive recommendation from the Drugs Group in November 2021, the HSE EMT subsequently approved Trastuzumab emtansine (Kadcyla®) for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.

4. Declaration of Interests / Nil Interest

5. Medicines for Consideration

i. 21008 Atezolizumab for small cell lung cancer (SCLC)

The Drugs Group previously considered Atezolizumab (Tecentriq®) in combination with Carboplatin and Etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) at its meeting in June 2021. The majority of the Drugs Group did not support reimbursement on that occasion given the cost-effectiveness estimates versus standard of care remained much higher than conventional willingness to pay thresholds, and reimbursement represented a substantial opportunity cost to the HSE.

In response to the previous recommendation of the Drugs Group, the applicant (Roche) submitted a substantially revised and enhanced commercial offer that considerably reduced the cost-effectiveness estimates versus standard of care chemotherapy regimens. The Group further acknowledged the unmet need for ES-SCLC, noting that standard treatment of this cancer had not significantly

changed over a number of decades. Considering this unmet need and the clinical evidence in the context of the substantial improvement in cost-effectiveness, the Drugs Group, by majority, recommended in favour of reimbursement.

ii. 21007 Atezolizumab for triple negative breast cancer (TNBC)

The Drugs Group previously considered Atezolizumab (Tecentriq®) in combination with nab-Paclitaxel for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease, at its meeting in April 2021. Reimbursement of this indication was not considered to be a cost-effective use of resources by the majority of Drugs Group members on that occasion.

In light of the Drugs Group recommendation, the applicant (Roche) submitted further information supporting the application including a substantially revised and enhanced commercial proposal which effected a sizeable reduction in the cost-effectiveness estimates previously considered by the Group. The Group considered the totality of evidence including the clinically meaningful improvement in overall survival in the licensed population, and the notable improvement in cost-effectiveness. The Drugs Group, by majority, recommended in favour of reimbursement.

iii. 21030 Neratinib as extended adjuvant treatment of early-stage breast cancer

Neratinib (Nerlynx®) for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant Trastuzumab-based therapy less than one year ago, was considered by the Drugs Group. The applicant (Pierre Fabre) proposed that restricted reimbursement be considered for a subpopulation of the licensed indication, namely whereby Trastuzumab is the only HER2-directed adjuvant treatment previously received, and patients must still have residual invasive disease in the breast or axilla following neoadjuvant treatment. The clinical and economic evidence was reviewed by the Group. The Group agreed that the applicant's proposed restricted subpopulation was appropriate given the limitations of the clinical trial. In light of this restricted subpopulation, Neratinib's unfavourable side effect profile (namely diarrhoea), and the recent developments in the treatment pathway for early breast cancer patients in Ireland, the Group considered that Neratinib would likely be a treatment option for a small, limited, and specific patient cohort. The Group noted that the substantial commercial offer [redacted] The Drugs Group supported restricted reimbursement for the subpopulation of the licensed Neratinib indication: Trastuzumab is the only HER2-directed adjuvant treatment previously received, and patients must still have residual invasive disease in the breast or axilla following neoadjuvant treatment.

iv. 20131 Pembrolizumab for relapsed or refractory classical Hodgkin Lymphoma

The Drugs Group considered Pembrolizumab (Keytruda®) for adult and paediatric patients aged 3 years and older with relapsed and refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or following at least 2 prior therapies when ASCT is not a treatment option. The Drugs Group noted that this application was for expanded reimbursement of Pembrolizumab for patients with classical Hodgkin Lymphoma, including a paediatric population. The Group reviewed the clinical evidence, noting a statistically significant improvement in progression-free survival (PFS) versus Brentuximab vedotin in KEYNOTE-204. The Drugs Group

noted that Pembrolizumab was [redacted] The Drugs Group unanimously recommended in favour of reimbursement.

v. 20132 Nivolumab + Ipilimumab + Platinum doublet chemotherapy for 1L mNSCLC

The Drugs Group considered Nivolumab (Opdivo®) in combination with Ipilimumab (Yervoy®) and 2 cycles of platinum-based chemotherapy for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) in adults whose tumours have no sensitising EGFR mutation or ALK translocation. The Drugs Group considered the current treatment landscape for first line metastatic NSCLC, and reviewed the clinical and economic evidence for this indication, including the impact of the commercial offer. The Drugs Group noted the recommendation of the National Cancer Control Programme Technology Review Committee (NCCP TRC) and considered that a limited number of patients would likely avail of this particular treatment regimen, given the reimbursement of alternative, less toxic immunotherapy treatment options. The Drugs Group unanimously recommended in favour of reimbursement.

6. AOB

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
Professor Risteárd Ó Laoide	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 Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	In attendance	In attendance
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
Ms Angela Fitzgerald	Acute Services Division (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*

*Parts of meeting and voting not attended

In attendance (non-voting):
Ms Kate Mulvenna
Dr. Lesley Tilson (NCPE)

Secretariat:
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan, Chief II Pharmacist, CPU PCRS