HSE Drugs Group – September 2021 Minutes

Meeting 2021.07: Tuesday 14th September 2021, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the May 2021 and June 2021 meetings 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 the following applications previously considered by the Drugs Group was given:

Patisiran for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy received a positive recommendation from the Drugs Group in May 2021. The HSE Executive Management Team (EMT) subsequently approved Patisiran for this indication subject to the implementation of a managed access programme to support appropriate prescribing of this medicine.

Tafamidis for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM) was considered by the Drugs Group in June 2021. The applicant (Pfizer) submitted an updated commercial offer that met the conditions required by the Drugs Group to support a positive recommendation. The HSE EMT subsequently approved Tafamidis for this indication subject to the implementation of a managed access programme to support appropriate prescribing of this medicine.

Midostaurin for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive was considered by the Drugs Group in June 2021. The applicant (Novartis) submitted an updated commercial offer that met the conditions required by the Drugs Group to support a positive recommendation. The HSE EMT subsequently approved this application.

Delafloxacin for the treatment of acute bacterial skin and skin structure infections (ABSSSI) received a positive recommendation from the Drugs Group in June 2021. The HSE EMT subsequently approved this application.

Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations were available for consideration by the HSE Drugs Group for the following applications: Nivolumab for the second-line treatment of oesophageal cancer, Dabrafenib+ Trametinib for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, and Polatuzumab vedotin for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

4. Declaration of Interests / Nil Interest

No potential conflicts were raised

5. Medicines for Consideration

i. 21015 Nivolumab 2L oesophageal cancer

The Drugs Group considered Nivolumab for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) after prior fluoropyrimidine and platinum-based chemotherapy. The Group reviewed the evidence from the pivotal ATTRACTION-3 study, in which a modest improvement in median overall survival of 2.5 months was observed for Nivolumab in comparison to Taxane monotherapy. The Group noted that the majority of patients enrolled in the trial were of Asian origin and the magnitude of benefit in a Western population had not been fully established. The Group considered that a full health technology assessment was unlikely to resolve their primary concerns with the clinical data. A high unmet need in this patient population who have a very poor prognosis was acknowledged by the Group. The modest clinical benefits coupled with the limitations of the clinical data were considered by the Drugs Group who, on balance, did not recommend reimbursement by majority.

ii. 21016 Dabrafenib + Trametinib for adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection

The Drugs Group unanimously recommended in favour of reimbursement of Dabrafenib in combination with Trametinib under the High Tech arrangements for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection. The Group noted the pivotal COMBI-AD trial met its primary endpoint with Dabrafenib + Trametinib demonstrating superior relapse-free survival compared to placebo. The Group noted the impact of the commercial proposal rendered [redacted]

iii. 21017 Polatuzumab vedotin for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

The Drugs Group unanimously recommended in favour of reimbursement of Polatuzumab vedotin in combination with Bendamustine and Rituximab for the treatment of adult patients with relapsed/ refractory DLBCL who are not candidates for haematopoietic stem cell transplant. The Group acknowledged the limited treatment options available to this patient cohort. The Group reviewed the clinical evidence from a phase Ib/II study (GO29365) in which Polatuzumab vedotin in combination with Bendamustine and Rituximab significantly increased complete response rate (primary endpoint) compared to Bendamustine and Rituximab alone. A median absolute overall survival (exploratory endpoint) benefit of 7.7 months was observed for the Polatuzumab vedotin arm over the control arm and was considered clinically meaningful by the Group. Notwithstanding the significant budget impact, the Group noted that Polatuzumab vedotin [redacted]

iv. 21018 Liraglutide for obesity

The Drugs Group considered Liraglutide (Saxenda®) as an adjunct to a reduced calorie diet and increased physical activity for weight management in adult patients with an initial body mass index of $\geq 35 kg/m^2$ with pre-diabetes and high risk of cardiovascular disease. It was noted that Liraglutide is anticipated to lose exclusivity in 2023. The Group reviewed the clinical and cost-effectiveness data for this application, noting this treatment could be considered [redacted] for this defined subgroup of the licensed population.

The Drugs Group unanimously recommended in favour of reimbursement for Liraglutide (Saxenda®) under the Community Drugs Schemes subject to the implementation of a managed access programme by the HSE Medicines Management Programme to support reimbursement in line with this defined subgroup of the licensed population (i.e. as an adjunct to a reduced calorie diet and increased physical activity for weight management in adult patients with an initial body mass index of $\geq 35 kg/m^2$ with pre-diabetes and high risk of cardiovascular disease). The Group recommended that the managed access programme should also incorporate guidance on treatment discontinuation for patients who have not lost ≥5% of their initial body weight after 12 weeks of treatment with Liraglutide 3mg.

v. 21019 Oral Semaglutide for type II diabetes mellitus

The Drugs Group considered oral Semaglutide (Rybelsus®) for the treatment of adults with insufficiently controlled Type II diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise: as monotherapy when Metformin is considered inappropriate due to intolerance or contraindications; or in combination with other medicinal products for the treatment of diabetes. The Drugs Group reviewed the clinical and cost-effectiveness evidence noting that the NCPE considered Empagliflozin as the main comparator for Semaglutide as the first oral GLP-1 receptor agonist. The Group noted that the economic evaluation did not satisfactorily demonstrate the cost-effectiveness of oral Semaglutide as compared to Empagliflozin, due to a number of modelling issues in capturing the long-term clinical outcomes associated with Empagliflozin therapy. The Group unanimously considered that a price premium for oral Semaglutide over Empagliflozin could not be supported. The Group unanimously agreed to recommend reimbursement of oral Semaglutide if price parity with oral comparators was achieved.

vi. 21020 Acalabrutinib for chronic lymphocytic leukaemia

The Drugs Group did not consider it necessary to review Acalabrutinib as monotherapy for the treatment of previously untreated Chronic Lymphocytic Leukaemia (CLL) in the presence of 17p deletion or TP53 mutation in adult patients unsuitable for chemoimmunotherapy (CIT); or as treatment of adult patients with CLL who have received at least one prior therapy. [redacted]

vii. 21021 Pembrolizumab for head & neck squamous cell carcinoma

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

viii. 21022 Gilteritinib for acute myeloid leukaemia

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

ix. 21023 Siponimod for secondary progressive multiple sclerosis

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

x. 21024 Cannabidiol for Lennox- Gastaut Syndrome

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

xi. 21025 Cannabidiol for Dravet Syndrome

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

xii. 21026 Esketamine for treatment-resistant major depressive disorder

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the October 2021 meeting.

5. AOB

   Dr. Kevin Kelleher confirmed that this was his last meeting due to his impending retirement. The Drugs Group and Secretariat wished Dr. Kevin Kelleher well in his retirement and recorded their thanks and appreciation for his valuable contributions through many complex Drugs Group deliberations.

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	In attendance*
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)	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)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance*
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	Apologies received
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

*Parts of meeting and voting not attended

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

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