HSE Drugs Group – October 2021 Minutes

Meeting 2021.08: Tuesday 12th October 2021, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the September 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 the following application previously considered by the Drugs Group was provided:

Onasemnogene abeparvovec (Zolgensma®) for the treatment of patients with spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type I, or pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene was considered by the Drugs Group at their June 2021 meeting. Pricing approval in Ireland was granted from the 8th October 2021 following joint assessment and negotiations under the Beneluxa Initiative.

In advance of the October 2021 meeting, the Chair and Drugs Group Secretariat agreed to include agenda item 21024b Cannabidiol for Tuberous Sclerosis Complex for review in tandem with the other two Cannabidiol agenda items in the interest of creating capacity and time efficiencies at future meetings.

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: Pembrolizumab for head and neck squamous cell carcinoma, and Gilteritinib for acute myeloid leukaemia.

4. Declaration of Interests / Nil Interest

5. Medicines for Consideration

i. 21021 Pembrolizumab for head & neck squamous cell carcinoma

The Drugs Group considered 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. The Drugs Group noted the limited treatment options and poor prognosis of this patient population. The Group reviewed the clinical evidence from the KEYNOTE-048 trial, noting the overall survival benefit in patients receiving Pembrolizumab as monotherapy, or in combination with chemotherapy, compared to the Cetuximab plus chemotherapy treatment arm. The Group acknowledged that treatment with either Pembrolizumab as monotherapy, or in combination with chemotherapy, would be determined by individual patient factors. The Group noted the impact of the commercial offer on the cost-effectiveness estimates. Following extensive deliberation, the Group

recommended in favour of reimbursement providing [redacted]

ii. 21022 Gilteritinib for acute myeloid leukaemia

The Drugs Group considered Gilteritinib (Xospata®) as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. The Group noted the higher relapse risk and poorer prognoses for AML patients with FLT3 mutations. Gilteritinib demonstrated a modest survival benefit over salvage chemotherapy in the pivotal phase III ADMIRAL study, with a median absolute survival benefit of 3.7 months. The Drugs Group considered Gilteritinib a high cost medicine with associated incremental cost-effectiveness ratios (ICERs) outside of conventional willingness to pay thresholds at the proposed list price for all relevant comparators. Following consideration of the totality of clinical and cost-effectiveness evidence, the Drugs Group agreed that the confidential price proposed was of insufficient magnitude for the Group to support reimbursement. The Drugs Group unanimously agreed that it would recommend reimbursement if [redacted]

iii. 21023 Siponimod for secondary progressive multiple sclerosis

The Drugs Group unanimously recommended in favour of Siponimod (Mayzent®) for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease - evidenced by relapses or imaging features of inflammatory activity. The EXPAND trial met its primary endpoint with the risk of 3-month confirmed disability progression (CDP) significantly lower with Siponimod compared to placebo. The Group reviewed the post hoc subgroup analysis of patients with active disease which reflects the licensed population. Time to onset of 3-month and 6-month CDP was delayed in Siponimod treated patients with active disease by 31% and 37% respectively compared to placebo. The Group noted the commercial offer rendered Siponimod [redacted] and unanimously recommended in favour of reimbursement.

iv. 21024 Cannabidiol for Lennox- Gastaut Syndrome

The Drugs Group unanimously recommended in favour of Cannabidiol (Epidyolex®) for use as adjunctive therapy of seizures associated with Lennox-Gastaut Syndrome (LGS), in conjunction with Clobazam, for patients 2 years of age and older. The Group recognised that LGS is a severe form of intractable epilepsy and despite currently available treatments, many patients continue to experience drug-resistant epilepsy. The need for new treatments with different modes of action was acknowledged. The Group noted the impact of the commercial offer on the cost-effectiveness and affordability of this treatment option. Their positive recommendation took into account the substantial unmet need for patient access to a proven, efficacious, safe and licensed Cannabidiol treatment in Ireland, coupled with the improvement in cost-effectiveness and affordability.

v. 21024b Cannabidiol for Tuberous Sclerosis Complex

The Drugs Group unanimously recommended in favour of Cannabidiol (Epidyolex®) for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older. Many patients do not achieve seizure control despite currently available treatment options. The Group noted the impact of the commercial offer on the affordability of this treatment option. Their positive recommendation took into account the substantial unmet need for patient access

to a proven, efficacious, safe and licensed Cannabidiol treatment in Ireland, coupled with the improved affordability of this medicine.

vi. 21025 Cannabidiol for Dravet Syndrome

The Drugs Group unanimously recommended in favour of Cannabidiol (Epidyolex®) for use as adjunctive therapy of seizures associated with Dravet Syndrome (DS), in conjunction with Clobazam, for patients 2 years of age and older. The Group recognised that Dravet Syndrome is a rare, debilitating, intractable paediatric epilepsy syndrome with a poor prognosis and substantial associated comorbidities. The need for alternative treatments with different modes of action was acknowledged. The Group noted the impact of the commercial offer on the cost-effectiveness and affordability of this treatment option. Their positive recommendation took into account the substantial unmet need for patient access to a proven, efficacious, safe and licensed Cannabidiol treatment in Ireland, coupled with the improvement in cost-effectiveness and affordability.

vii. 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 November 2021 meeting.

viii. 21027 Pembrolizumab + Axitinib for renal cell carcinoma

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

ix. 21028 Baricitinib for atopic dermatitis

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

x. 21029 Trastuzumab emtansine for adjuvant treatment of HER-2 positive early breast cancer

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

5. AOB

Following on from discussions pertaining to quorum at the May 2021 Drugs Group meeting, and following engagements with the HSE Chief Clinical Officer in relation to same, the Chair provided an update to the Group. The Drugs Group proposed revisions to the current Terms of Reference regarding the establishment of meeting quorums were accepted. It was agreed that the revised Terms of Reference would be circulated at the next meeting.

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)	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	Public Interest Member	Apologies received
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
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	In attendance

*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