HSE Drugs Group – January 2020 Minutes

Meeting 2020.01: Tuesday 14th January, 14.00
Indigo Room, Dr.Steevens' Hospital, Kilmainham, Dublin 8

1. Draft Minutes for Consideration

The minutes of the December 2019 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

CPU provided the members with an update in relation to items previously considered.

4. Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations to the HSE Drugs Group were considered for the applicable medicines on the agenda.

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

6. Medicines for Consideration

i. 19019 Mannitol for Cystic Fibrosis

The Drugs Group considered an updated application submitted by the applicant in 2019. The Drugs Group unanimously did not support reimbursement of Mannitol under the High Tech arrangements, for the treatment of cystic fibrosis in adults aged 18 years and above as an add-on therapy to best standard of care. The Group reviewed the totality of the clinical evidence, including the additional evidence submitted (Study DPM-CF-303), and agreed the data was not sufficiently robust to recommend in favour of reimbursement of Mannitol.

ii. 19020 Tildrakizumab for Plaque Psoriasis

The Drugs Group unanimously did not support reimbursement of Tildrakizumab under the High Tech arrangements for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. The Group noted the multiple biologic comparators licensed and reimbursed for plaque psoriasis, and that Etanercept was the only comparator with head to head evidence versus Tildrakizumab. The proposed commercial offer from the applicant was reviewed in light of other biologic comparators. The Group determined a pricing threshold at which they would issue a positive recommendation for Tildrakizumab. Alternatively, the Group agreed that a full Heath Technology Assessment should be conducted to determine if a clinical benefit existed for Tildrakizumab in comparison to cheaper biologics, and its associated value if so.

iii. 19021 Erenumab for Migraine

The Drugs Group considered reimbursement of Erenumab under High Tech arrangements for a defined patient subgroup of the full licensed indication - the prophylaxis of chronic migraine in adults who have failed 3 or more prophylactic treatments. The Group noted the unmet need for

alternative and effective treatments in this patient group. The Group reviewed the clinical and cost-effectiveness evidence, noting that Erenumab appeared to be a cost-effective treatment option in this patient cohort. The Drugs Group were minded to recommend reimbursement for the cohort of chronic migraine patients providing:

- An individual patient approval system be put in place to enable reimbursement for patients meeting predefined conditions via a managed access protocol in conjunction with the HSE Medicines Management Programme [redacted]

iv. 19022 Nivolumab for Adjuvant Melanoma

The Drugs Group considered Nivolumab as monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. The Group noted the improvement in recurrence free survival versus Ipilimumab in the pivotal study CheckMate 238. The standard of care in Ireland is routine surveillance. Currently approved therapies are associated with significant toxicities. The Group noted the unmet need for safe and effective treatments for adjuvant melanoma and considered Nivolumab an improved therapeutic option. The Group noted that Nivolumab [redacted] The Drugs Group unanimously supported reimbursement of Nivolumab for this indication.

v. 18030 Nivolumab for 2nd line Urothelial Carcinoma

The Drugs Group considered Nivolumab as monotherapy for the treatment of locally advanced unresectable or metastatic urothelial carcinoma after failure of prior platinum-containing therapy. The Group noted the significant uncertainty from the two single arm, open-label, phase II trials: CheckMate 275 & CheckMate 032. The Group acknowledged the challenges in assessing the cost-effectiveness given the uncertainties in the clinical evidence. The Group unanimously did not support reimbursement of Nivolumab for this indication.

7. AOB / Members Time

The date of the next meeting was confirmed as 11th February 2020.

Appendix 1: Members Present

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)	In attendance
Ms Fiona Bonas	Interim National Director of the National Cancer Control Programme	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
Position Vacant	Public Interest Member / Ethicist	Position Vacant
Mr Michael Power	Public Interest Member	Apologies received
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance
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	Apologies received

In attendance (non-voting):
Professor Michael Barry (NCPE)
Ms Kate Mulvenna (KM), Head of Pharmacy Function/ CPU, PCRS

Secretariat:
Ms Maria Daly (MD), Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan (FM), Senior Pharmacist, CPU PCRS