HSE Drugs Group – November 2019 Minutes

Meeting 2019.08: Tuesday 12th November, 14.00
Boardroom 1, Dargan Building, Heuston South Quarter, Military Road, Kilmainham, D8

1. Draft Minutes for Consideration

The minutes of the September 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

[redacted]

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. 19008 Pertuzumab for Adjuvant Breast Cancer

The Drugs Group unanimously did not support reimbursement of Pertuzumab under the Oncology Drugs Management System in combination with Trastuzumab and chemotherapy in the adjuvant treatment of HER2-positive early breast cancer at high risk of recurrence. The Drugs Group considered the clinical and cost-effectiveness evidence at length. They noted the uncertainty regarding the use of Invasive Disease-Free Survival (IDFS) as a surrogate marker for longer term outcomes with the final analysis expected in 2023. Overall Survival was immature at the time of primary analysis with no apparent differences between treatment arms. The Group reviewed the pre-planned subgroup analysis for IDFS with Pertuzumab appearing more beneficial in node-positive patients. In the context of the clinical evidence and uncertainty in the cost-effectiveness evidence and budget impact, the Drugs Group did not recommend in favour of reimbursement.

ii. 18009 Teduglutide for Short Bowel Syndrome (SBS)

The Drugs Group recommended, by majority, in favour of reimbursement of Teduglutide under the High Tech arrangements for the treatment of patients with Short Bowel Syndrome (SBS). The group recognised the unmet need for treatments in SBS and the positive recommendation of the Rare Diseases Technology Review Committee to reimburse the orphan drug Teduglutide. The Group considered the clinical evidence, recognising the potential cost-offsets from a reduced requirement for parenteral nutrition and IV fluids. The Group agreed that Teduglutide offered a new treatment option for SBS and on the basis of the commercial offer recommended in favour of its reimbursement.

iii. 19012 Daratumumab +Lenalidomide + Dexamethasone for Multiple Myeloma

The HSE Drugs Group unanimously did not support reimbursement of Daratumumab in combination with Lenalidomide and Dexamethasone (DAR-LEN-DEX) under the Oncology Drugs Management System for the treatment of multiple myeloma. The Drugs Group noted that Daratumumab monotherapy had previously received a positive recommendation and was now subsequently reimbursed. Daratumumab in combination with Bortezomib and Dexamethasone received a positive recommendation from the Drugs Group in May 2019. The Group noted the NCPE had previously recommended a full pharmacoeconomic assessment in 2017. Janssen had not proceeded with this assessment at that time due to the challenges presented in demonstrating cost-effectiveness with this regimen. The Drugs Group recognised significant uncertainty remained in relation to the budget impact despite the proposed commercial offer. The Drugs Group considered that a HTA was necessary to evaluate cost-effectiveness and that a robust deliberation on DAR-LEN-DEX could not take place in its absence.

iv. 19011 Lesinurad for Gout

The Drugs Group considered the clinical evidence, noting that the clinical relevance of the surrogate endpoint of serum Uric Acid is unclear. Improvement of gout flares and tophi reduction after 12 months was not statistically significant versus placebo. The Group also noted there was a lack of evidence to support the modelling assumption used in the cost-effectiveness analysis that lowering serum uric acid extends life. The Drugs Group unanimously did not support reimbursement of Lesinurad under the Community Drugs Schemes.

v. 19010 Cerliponase alfa for neuronal ceroid lipofuscinosis type 2 (CLN2 disease)

The Drugs Group considered the unmet need of the ultra-rare CLN2 disease. The rapid and severe progression of the disease leading to death in early adolescence was recognised. Notwithstanding the poor cost-effectiveness, the Group recommended by majority in favour of reimbursement of Cerliponase alfa as a hospital medicine for the treatment of CLN2 disease.

vi. 19015 Rivaroxaban for coronary artery disease (CAD) or peripheral artery disease (PAD)

The Drugs Group deferred consideration of this therapy due to time constraints.

7. AOB / Members Time

i. Naltrexone/Bupropion (Mysimba®) representations

The Drugs Group reviewed representations received from the pharmaceutical company following the issuance of a notice of proposal not to reimburse in February 2019. The concerns previously expressed by the Drugs Group remained as the pharmaceutical company did not present any new evidence to address same. The Drugs Group unanimously supported their previous recommendation not to reimburse this medicine.

ii. Doravirine (Pifeltro®)

The Drugs Group agreed that budget impacts of this magnitude did not require their consideration.

iii. Levodopa/Carbidopa (Duodopa®)

The Drugs Group agreed that Duodopa® would require full consideration on a future agenda for due deliberation.

iv. Obeticholic Acid for primary Biliary Cholangitis/ Cirrhosis (PBC)

The HSE had previously advised Intercept to re-engage with the NCPE in light of more mature data outputs for Obeticholic Acid. It was agreed that a summary of the output of this engagement with the NCPE should be presented to the Drugs Group.

v. Proposed dates for 2020 meetings were circulated.

vi. The date of the next meeting was confirmed as 16th December 2019.

Appendix 1: Members Present

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Ms Kate Mulvenna	Primary Care Reimbursement Service, Head of Pharmacy Function, For 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
Dr Jerome Coffey	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)	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)	Apologies received
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	By Teleconference
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

In attendance (non-voting):
Dr. Roisin Adams (NCPE)

Secretariat:
Mr Shaun Flanagan (SF), Primary Care Reimbursement Service (Assistant National Director)-pending completion of outstanding matters
Ms Jennifer McCartan (JMcC), Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan (FM), Senior Pharmacist, CPU PCRS