HSE Drugs Group – February 2021 Minutes

Meeting 2021.02: Tuesday 9th February 2021, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the January 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

Applications that were reviewed at the December 2020 and January 2021 meetings with positive recommendations were being progressed with approval and funding now supported by the HSE EMT. A significant number of new medicines / new uses of medicines have now been made available for reimbursement as of the 1st February 2021.

Updates / reports from TRCs

The Rare Diseases Technology Review Committee's (RDTRC) report and recommendations in relation to Burosumab was available for the HSE Drugs Group and considered in the discussions for this medicine.

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendation in relation to Talazoparib was available for the HSE Drugs Group and considered in the discussions for this medicine.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 20016 Burosumab for the treatment of X-linked hypophosphataemia (XLH) in children

Burosumab was previously considered by the Drugs Group in July 2020 and subsequently referred by the Group to the Rare Diseases Technology Review Committee (RDTRC) for further patient and clinician engagement in order to assist the Drugs Group in making its recommendation.

The Drugs Group reviewed the recommendations of the RDTRC, along with the final HTA report, the outputs of commercial negotiations, and the patient group submissions received from XLH UK. The final incremental cost-effectiveness ratio (ICER) versus standard of care of [redacted] proposed in the commercial offering.

The Drugs Group, in the majority, supported reimbursement of Burosumab for the treatment of XLH with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons. The majority opinion of the group was, in the main, based on the clinical efficacy data from the pivotal studies and the high and significant unmet need for this cohort of children with a rare disease that is associated with significant morbidity and negatively impacts on quality of life.

ii. 19015 Rivaroxaban for coronary artery disease (CAD)/ peripheral artery disease (PAD)

In September 2020 the Drugs Group agreed unanimously that it could not recommend funding on the basis of the clinical evidence presented and the anticipated budget impact that was uncertain but likely to be substantial. In response the applicant submitted [redacted]

The Drugs Group in the majority supported reimbursement that was conditional on the enhanced commercial offer [redacted] and a managed access programme being implemented that would ensure eligible patients with CAD or PAD were otherwise optimally treated on other preventative therapies prior to Rivaroxaban initiation.

iii. 21001 Talazoparib for advanced or metastatic breast cancer with a germline BRCA1/2-mutation

Talazoparib is an orally administered systemic anticancer treatment indicated for adult patients with a genetic predisposition and at higher risk of developing breast cancer. The place in therapy may vary depending on the biological features of the disease but it could delay the use of systemic cytotoxic chemotherapy in a locally advanced or metastatic setting in patients considered eligible to receive treatment with Talazoparib.

The pivotal PIII study EMBRACA (n=431) met its primary endpoint with Talazoparib demonstrating a progression free survival (PFS) benefit when compared with investigator choice of chemotherapy.

Talazoparib is 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 comparisons.

The Drugs Group agreed that it could not support reimbursement of Talazoparib at the confidential price proposed as it was of insufficient magnitude for Talazopraib to be considered cost-effective. The Drugs Group unanimously agreed that it would support funding if [redacted]

iv. 21002 Voretigene neparvovec for inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations

The Drugs Group requested Patient and Clinician Engagement input via the Rare Diseases Technology Review Committee (RDTRC) in the first instance to assist the group in making its recommendation regarding reimbursement of Voretigene neparvovec.

The Drugs Group sought specifically a Prescribing Guideline for Voretigene neparvovec that would include initiation and eligibility criteria if appropriate. The Guideline would also include outcome monitoring. Such outcomes would be considered by the RDTRC to be feasible to collect and report upon at suitable intervals [redacted] The Group would also welcome any recommendations or additional information that the RDTRC can provide, which will be duly considered in the deliberative processes for this medicine.

v. 21003 Lenvatinib for hepatocellular carcinoma (HCC)

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

vi. 21004 Apalutamide for non-metastatic castration-resistant prostate cancer (nmCRPC)

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

vii. 21005 Fremanezumab for migraine prophylaxis

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

6. AOB

Shaun Flanagan (AND PCRS) informed the Group of the appointment of Ms. Ellen McGrath to Chief I Pharmacist, Head of the Corporate Pharmaceutical Unit (interim) which is expected once the HR processes have completed.

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	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	In attendance

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
Ms Ellen McGrath, Chief II Pharmacist, CPU PCRS