HSE Drugs Group – July 2020 Minutes

Meeting 2020.06: Tuesday 14th July, 14.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the June 2020 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 at the EMT which were previously considered by the group. The group were made aware that EMT approved one new medicine and two license extensions (new use).

4. Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations in relation to Durvalumab and Osimertinib were available for the HSE Drugs Group and considered in the discussions for these medicines.

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

6. Medicines for Consideration

i. 20014 Patisiran for hereditary transthyretin-mediated amyloidosis

The Drugs Group reviewed the final HTA report, along with the outputs of commercial negotiations, and the patient group submission received during the HTA process for Patisiran (Onpattro®).

The Drugs Group were unable to progress a recommendation that was supportive of reimbursement on the basis of the evidence available. The Drugs Group considered that the magnitude of clinical effect was insufficient in light of the budget impact and the failure to demonstrate cost effectiveness.

The group considered that additional information was required and requested further Patient and Clinician Engagement input via the HSE Rare Diseases Technology Review Committee (RDTRC). The group committed to reviewing the output of the RDTRC at the earliest opportunity and consider a reimbursement recommendation at that time.

ii. 20015 Lutetium (^{177} Lu) Oxodotreotide for gasteroenteropancreatic neuroendocrine tumours

The Drugs Group reviewed the evidence in relation to Lutetium (^{177}Lu) Oxodotreotide (Lutathera®). Issues covered in the discussion included the:

- evidence available from the pivotal studies for market authorisation (MA) and its generalisability to Irish clinical practice
- the evidence submitted in the Health Technology Assessment to support reimbursement

- the current treatment options, international evidence based guidelines and the unmet need for patients with this rare malignancy
- the current treatment pathway in Ireland
- some uncertainties around the potential budget impact

The Group unanimously came to the conclusion that it required additional information before it could make a recommendation. The group requested the considerations from the oncology specialists (via the NCCP TRC) as well as more detailed treatment costs that may have been historically covered by the Treatment Abroad Scheme (TAS) when a comparable product was classified as a device. In addition to the information requested the Drugs Group instructed the CPU to re-engage with Advanced Accelerator Solutions (the applicant) to seek enhanced commercial terms.

iii. 20016 Burosumab for X-linked hypophosphataemia

The Drugs Group reviewed the final HTA report, along with the outputs of commercial negotiations which produced [redacted], and the patient group submission from XLH UK which was received during the HTA process for Burosumab (Crysvita®).

The Drugs Group were unable to progress a positive recommendation on the basis of the evidence available in addition to a high budget impact which was subject to significant uncertainty and a failure to demonstrate cost-effectiveness. The Drugs Group considered that the magnitude of clinical effect was uncertain, in particular for the claimed long term benefits, for which there is no supportive evidence.

The group considered that additional information was required and requested further Patient and Clinician Engagement input via the HSE Rare Diseases Technology Review Committee (RDTRC). The group committed to reviewing the output of the RDTRC at the earliest opportunity and consider a reimbursement recommendation at that time.

iv. 20017 Durvalumab for advanced non-small cell lung cancer (NSCLC) consolidation treatment

The Drugs Group unanimously recommended in favour of reimbursement of Durvalumab (Imfinzi®) monotherapy under the Oncology Drug Management System (ODMS) for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on $\geq$ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy.

In the pivotal PIII study PACIFIC (n=713) Durvalumab was associated with a significant improvement in both progression free survival (PFS) and overall survival (OS) compared with placebo. Irish patients with advanced NSCLC that has not progressed post definitive chemoradiation are expected to undergo routine surveillance as post treatment follow-up. The Drugs Group was therefore satisfied that use of placebo in the comparator arm was reflective of current standard of care (SoC) in Ireland.

[redacted]

v. 20018 Osimertinib for 1L EGFR mutation positive non-small cell lung cancer (NSCLC)

The Drugs Group unanimously recommended in favour of reimbursement of Osimertinib (Tagrisso®) under High Tech arrangements for the first-line (1L) treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations

In the pivotal PIII study FLAURA (n=556) Osimertinib was associated with a significant and clinically meaningful improvement in both progression free survival (PFS) and overall survival (OS) when compared with 1st generation oral EGFR Tyrosine Kinase Inhibitors (TKI) Erlotinib and Gefitinib. The group noted that Erlotinib is currently the most frequently prescribed EGFR TKI for the 1L treatment of advanced EGFR mutation positive NSCLC in Ireland.

[redacted]

7. AOB / Members Time
    i. Kate Mulvenna informed the Group that the HSE EMT will be ratifying the membership of Drugs Group for a further period to include replacement of vacancies
    ii. The Drugs Group recorded their thanks and appreciation to Ms Fiona Bonas for her contributions as a member of the Drugs Group during her time as interim National Director of the National Cancer Control Programme (NCCP).

Appendix 1: Members Present on Microsoft Teams

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	Apologies received
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 (Chair)
Ms Fiona Bonas	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)	Apologies received
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

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

Secretariat:
Ms Fiona Mulligan, Senior Pharmacist, CPU PCRS
Ms Maria Daly, Chief II Pharmacist, CPU PCRS
Ms Ellen McGrath, Chief II Pharmacist, CPU PCRS