HSE Drugs Group – October 2024 Minutes
Meeting 2024.09: Tuesday 8th October 2024, 14.00 – 15.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the September 2024 meeting were considered and approved.

2. Matters arising / Update on Medicines considered at previous meeting

i. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from the September 2024 meeting progressed to the HSE Senior Leadership Team (SLT) for consideration had been supported.

ii. The Group noted that the HSE SLT had recently reviewed Drugs Group membership and issued individual formal appointment and renewal letters to members as relevant.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Nivolumab (Opdivo®) for the adjuvant treatment of muscle invasive urothelial carcinoma (MIUC) (NCPE HTA ID: 22046)

The Drugs Group considered Nivolumab (Opdivo®) as monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥ 1%, who are at high risk of recurrence after undergoing radical resection of MIUC. The Group acknowledged the treatment option limitations for patients with high risk residual disease following surgery, especially patients for whom platinum-based adjuvant chemotherapy is unsuitable. The Group noted that Nivolumab represents the first immunotherapy to be licensed for the adjuvant treatment of MIUC. The clinical evidence was reviewed by the Group including adjuvant therapy recommendations from international guidelines and the NCCP TRC recommendation. The Group noted the considerable Nivolumab disease-free survival benefit observed in the pivotal trial versus routine surveillance but noted the uncertainty associated with the immature overall survival data based on currently available clinical evidence. At list price, the ICER for Nivolumab was €20,412/QALY (Applicant) and €34,103/QALY (NCPE) versus routine surveillance. The Group acknowledged the impact of the commercial proposal on cost-effectiveness estimates which helped to address some of the uncertainties in the clinical evidence. Following deliberations, the Group unanimously agreed to recommend reimbursement of Nivolumab (Opdivo®), under the Oncology Drug Management System (ODMS), as monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥ 1%, who are at high risk of recurrence after undergoing radical resection of MIUC, providing patients are unsuitable for adjuvant treatment with platinum-based chemotherapy.

ii. Pembrolizumab (Keytruda®) for the adjuvant treatment of adults and adolescents aged 12 years and older with stage IIB or IIC melanoma (NCPE HTA ID: 22042)

The Drugs Group considered Pembrolizumab (Keytruda®) as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with stage IIB or IIC melanoma and who have undergone complete resection. The Group reviewed the clinical and economic evidence for this patient population, including the outputs of commercial negotiations and the NCCP TRC recommendation. Evidence from the Patient Organisation (Melanoma Support Ireland) was also reviewed by the Group which highlighted that patients with stage IIB and IIC melanoma have a similar prognosis as that for patients with stage III melanoma and have a similar or greater risk of recurrence than patients with stage IIIA & IIIB melanoma. The Group acknowledged the impact of

the commercial proposal which rendered Pembrolizumab [redacted] The Group unanimously recommended in favour of reimbursement of Pembrolizumab (Keytruda®) under the Oncology Drug Management System (ODMS), for this indication on the basis of the unmet need, clinical evidence and cost effectiveness evidence, notwithstanding the substantial budget impact.

iii. Pembrolizumab (Keytruda®) for the adjuvant treatment of renal cell carcinoma (NCPE HTA ID: 22026)

The Drugs Group considered Pembrolizumab (Keytruda®) as monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. The Group noted current standard of care in Ireland involves active surveillance with many patients with intermediate-high or high-risk lesions experiencing recurrence within two to three years following surgery.The Group reviewed the clinical evidence taking into consideration the recommendation from the NCCP TRC. In reviewing the economic evidence, the Group noted the improvement in both the applicant and NCPE's cost effectiveness estimates when incorporating the commercial offer. Pembrolizumab was considered [redacted] Following deliberations, the Group unanimously recommended in favour of reimbursement of Pembrolizumab (Keytruda®) under the Oncology Drug Management System (ODMS) for this indication on the basis of the unmet need, clinical evidence and cost effectiveness evidence, notwithstanding the substantial budget impact

iv. Liraglutide (Saxenda®) for weight management in adolescents (12 -17 years) (NCPE HTA ID: 24001)

The Drugs Group considered Liraglutide (Saxenda®) as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 to 17 years with: obesity (BMI corresponding to ≥30 kg/m^2 for adults by international cut-off points) and body weight above 60 kg. The Group noted that following consultation with the National Clinical Programme for Obesity, the applicant was seeking restricted reimbursement for adolescent patients aligned to the criteria for the severe and complex obese population set out in Children's Health Ireland (CHI) Complex Obesity Service referral form. The Group acknowledged that childhood obesity is associated with a number of comorbid conditions and psychological problems. Pharmacotherapy may serve as a valuable adjunct to lifestyle intervention in achieving and sustaining weight loss, and facilitating healthier lifestyle habits in those identified as having the greatest unmet need. The Group reviewed the available clinical and economic evidence as well as the output of commercial negotiations. It was noted that Liraglutide (Saxenda®) is available for reimbursement under the Community Drug Schemes from 1st January 2023 for a subgroup of the licensed adult population meeting eligibility as per a HSE Managed Access Protocol. The HSE Drugs Group unanimously recommended in favour of restricted reimbursement of Liraglutide (Saxenda®), under Community Drug Schemes, as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 to 17 years, subject to specialist initiation and the establishment of a managed access protocol in line with Children's Health Ireland (CHI) Complex Obesity Service referral criteria.

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	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 (Acting chair)
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Ms Mary Ruth Hoban	Assistant Director of Nursing and Midwifery (Prescribing) HSE West	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance*
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	Apologies received
Ms Carol Ivory for Ms Catherine Clarke	General Manager, Specialist Acute Services, Acute Operations, HSE for Strategy & Planning – Unscheduled Care (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

*Parts of meeting and/or some voting not attended

In attendance (non-voting):
Professor Michael Barry (NCPE)

Secretariat:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS