National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**Sept 22nd 2020 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Apalutamide (Erleada) -not discussed due to time pressures
	Daunorubicin and Cytarabine (Vyxeos)
	Lutetium oxodotreotide (Lutathera)
	Olaparib (Lynparza)
	Pembrolizumab (Keytruda)

TEXT FOR REDACTION DUE TO DELIBERATIVE PROCESS HIGHLIGHTED IN YELLOW

TEXT FOR REDACTION DUE TO COMMERCIAL SENSITIVITY IS HIGHLIGHTED IN PINK

TEXT FOR REDACTION DUE TO CONFIDENTIALITY IS HIGHLIGHTED IN BLUE

Attendance:

Members present		
Dr. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr. Deirdre O'Mahony	Medical Oncologist, Bon Secour Hospital, Cork: ISMO nominee	
Dr. Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative	By 'phone
Dr. Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative	By 'phone
Dr. Patricia Harrington	Head of Assessment, HTA Directorate: HIQA nominee	By 'phone
Ms. Patricia Heckmann	NCCP Chief Pharmacist **- Chair**	By 'phone
Ms. Ellen McGrath	Chief Pharmacist; HSE Corporate Pharmaceutical Unit	By 'phone

Non-member invited specialists present		
Dr. Aileen Flavin	Clinical Lead for Radiation Oncology, CUH	By 'phone
Dr. Mark Doherty	Medical Oncologist, SVUH	By 'phone

Apologies (members)	
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee
Dr. Deirdre Murray	NCCP Health Intelligence
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative
Dr. Eve O'Toole	Research Group Lead, NCCP
Dr. Linda Coate	Medical Oncologist, University Hospital Limerick: ISMO nominee
NCPE representative	National Centre for Pharmacoeconomics (NCPE)

Observers present	
Ms. AnneMarie De Frein	Deputy Chief Pharmacist, NCCP

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded of the confidentiality of documentation and discussions. In addition to the conflict of interest forms signed by all members previously, members were asked to raise any conflicts of interest that they had in relation to any drug for discussion prior to the commencement of the discussion of that item.	
2	**Notes of previous meeting and matters arising**	
	The notes of the previous meeting on July 6th 2020 were not discussed due to time pressures.	
3	**Drugs/Technologies for consideration**	
	Apalutamide (Erleada ®) *Treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease* This item was not discussed due to time pressure and will be added to the agenda for the next meeting. **Daunorubicin and Cytarabine (Vyxeosi ®) (Ref. TRC 073)** *For the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)* The committee members considered that there has been very little new treatments for this patient cohort and this treatment represents a clear benefit compared to existing options. This is likely to be a small patient group. Having considered the clinical efficacy of the indication and the unmet clinical need in this patient cohort, it was agreed unanimously to recommend approval of this indication to the HSE Drugs Group. (Decision: TRC073) **Lutetium oxodotreotide (Lutathera®) (Ref. TRC 074)** *Treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP NETs) in adults* The clinical aspects of this application were detailed by the two invited experts, Dr Mark Doherty as a medical oncologist with specialist interest in NETs and Dr Aileen Flavin as the National Lead for Radiation Oncology. Clinically, it was detailed that the NETTER-1 study has shown a clear benefit for patients and that this is an internationally accepted standard of care for this disease. It was acknowledged that patients have been accessing this treatment via the treatment abroad scheme for many years. Historically, this service used a product that was unlicensed but Lutetium oxodotreotide represents a licensed product which is used by the international service providers. It is preferable from an equity perspective to have this treatment available in Ireland, as it was noted that not all patients may be in a position to travel to access this. This is of particular importance considering Covid-19 restrictions that may be in place.	NCCP to communicate recommendations to HSE Drugs Group.

It was noted that the trial design predated the availability of the targeted therapies which may have been a more acceptable comparator.

Considering this is considered an international standard if care for this disease, an area of unmet need in Ireland and that there is some inequity in access currently, the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group.

(Decision: TRC074)

Olaparib (Lynparza®) (Ref. TRC 075)

As monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum based chemotherapy

The clinical benefits were outlined including that consistent benefit was seen in all patients included in the phase three trial including a reduction in the number of patients progressing from 8.4% to 3.5%. It was detailed that this is felt to be a very important option for BRCAm ovarian cancer patients and is an international standard of care.

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It was discussed that this application is associated with a different product formulation and that measures would need to be put in place to ensure safety for patients as the products are not interchangable.

The committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group.

(Decision: TRC075)

Olaparib (Lynparza®)

As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy

This item was not discussed due to time pressure and will be added to the agenda for the next meeting.

Pembrolizumab (Keytruda®) (Ref. TRC 076)

As monotherapy is indicated for the adjuvant treatment of melanoma in adults with lymph node involvement who have undergone complete resection

The committee members considered that this was already discussed at HSE Drugs Group and that the Drugs Group members had requested the input of the expert clinicians with regard to other applications for this indication.

The clinician members of the committee members agreed with the view of the expert clinicians that the priority is to have an available option reimbursed for this patient cohort.

The committee members agreed by majority to recommend approval of this

	indication to the HSE Drugs Group, if it was deemed to be cost equivalent with other options in this indication as these were felt to be otherwise equivalent. **(Decision: TRC076)**	
4	**Update on other drugs in the reimbursement process**	
	An update on the drugs that are in the reimbursement process was circulated to members in advance of the meeting.	
5	**Next meeting**	
	The proposed date for the next meeting dates is in October, details to be circulated to the group.	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 6.00pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
20/04	22/09/2020	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Complete