National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**Nov 4th 2019 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Daratumumab (Darzalex®)
	Nivolumab (Opdivo®)
	Pembrolizumab(Keytruda®) (a number of indications)

TEXT FOR REDACTION DUE TO DELIBERATIVE PROCESS HIGHLIGHTED IN YELLOW

TEXT FOR REDACTION DUE TO COMMERCIAL SENSITIVITY IS HIGHLIGHTED IN PINK

Attendance:

Members present		
Dr. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	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**	
Dr. Deirdre Murray	NCCP Health Intelligence	
Dr. Deirdre O'Mahony	Medical Oncologist, Bon Secour Hospital, Cork: ISMO nominee	By 'phone

Non-member invited specialists present	
None	
Apologies (members)	
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative
Dr. Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative
Dr. Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative
Dr. Eve O'Toole	Research Group Lead, NCCP
Dr. Ray McDermott	Medical Oncologist, TUH/St. Vincent's: ISMO nominee
Mr. Shaun Flanagan	Chief Pharmacist; HSE Corporate Pharmaceutical Unit
NCPE representative	National Centre for Pharmacoeconomics (NCPE)
Observers present	
Ms. AnneMarie De Frein	Deputy Chief Pharmacist, NCCP
Dr. Jerome Coffey	National Director, 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. No conflicts were raised during the meeting.	
2	**Notes of previous meeting and matters arising**	
	The notes of the meeting on Sept 3rd 2019 were approved.	
3	**Drugs/Technologies for consideration**	
	Daratumumab (Darzalex ®) *Daratumumab in combination with lenalidomide and dexamethasone (LEN+DEX) for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy* The committee members considered that this combination therapy offers an alternate option to this patient cohort, noting that the study showed the longest progression free survival data to date. The committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group acknowledging that this application will not be subject to a HTA. (Decision: TRC060) **Nivolumab (Opdivo ®)** *As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection* The committee members considered that this drug provides an option in an area of unmet need for this patient cohort. In considering the clinical efficacay, it was noted that no overall survival has been seen to date but an acceptable toxicity profile and an improved relapse free survival are shown. This indication is a priority for melanoma clinicians and for patient advocacy groups. It was acknowledged that there is a substantial budget impact associated with this application but that the commercial negotiations with the company are ongoing. 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: TRC061) **Pembrolizumab (Keytruda ®)** *As monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy*	

	The committee members considered the clinical efficacy of this second line indication. It was felt that there is a substantial unmet need in this patient cohort who have relapsed post-platinum containing treatment. A clear improvement has been seen in overall survival rates from the Keynote 045 study. The advantages of this treatment are clinically significant for this patient cohort. 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: TRC062)	
	Pembrolizumab (Keytruda ®) *As monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy whose tumours express PD-L1 with a combined positive score (CPS) ≥10* The committee members considered the clinical efficacy of the indication. It was recognised that this is a modification of the original reimbursement application following a revised license approval by the EMA. As a result, this is unlikely to be a large cohort of patients as only those patients who are not eligible for cisplatin-containing chemotherapy whose tumours express PD-L1 with a combined positive score (CPS) ≥10 are now eligible. This represents a patient cohort with limited alternate options. The committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group acknowledging that this application will not be subject to a HTA. (Decision: TRC063)	
	Pembrolizumab (Keytruda ®) *Pembrolizumab In Combination with CARBOplatin and Either PACLitaxel or Nab-PACLitaxel for the First-Line Treatment of Patients with Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)* The committee members considered the clinical efficacy of this indication and considered that pembrolizumab in combination with chemotherapy in this patient cohort offers no unexpected toxicity and an improved overall survival. The clinicians were happy that this use would be limited to in combination with carboplatin and paclitaxel only as one way to reduce the associated costs with this treatment. It was also felt that there may be a potential offset in costs against the use of immunotherapy in second-line lung cancer treatment but acknowledged that this is not currently quantifiable. Having considered the clinical efficacy of the indication and with an agreement to limit the use of the combination chemotherapy to paclitaxel and carboplatin only, it was agreed unanimously to recommend approval of this indication to the HSE Drugs Group acknowledging that this application will not be subject to a HTA. (Decision: TRC064)	
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**	
	Date will be advised. It was agreed to trial an earlier start time of 4.30 for the next meeting.	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 6.30pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
19/03	04/11/19	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	