National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**Sept 3rd 2019 at 5.00pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Carfilzomib (Kyprolis®)
	Dacomitinib (Vizimpro®)
	Daratumumab (Darzalex®)
	Niraparib (Zejula®)
	Osimertinib (Tagrisso®)
	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		
NCPE representative	National Centre for Pharmacoeconomics (NCPE) *Not present for all decisions	By 'phone
Dr. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative	By 'phone
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	
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	By 'phone
Dr. Deirdre O'Mahony (DOM)	Medical Oncologist, Cork University Hospital: ISMO nominee *Not present for all decisions	By 'phone
Dr. Eve O'Toole	Research Group Lead, NCCP	
Non-member invited specialists present		
None		
Apologies (members)		
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	
Observers present		
Ms. AnneMarie De Frein	Deputy Chief Pharmacist, NCCP	
Dr. Jerome Coffey	National Director, NCCP	
Mr. Keith Comiskey	National Programme manager, STP, 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 March 26th 2019 were approved.	
3	**Drugs/Technologies for consideration**	
	Carfilzomib (Kyprolis®) *In combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy* The committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group acknowledging that this application has already been discussed by the Drugs Group in terms of its clinical and pharmacoeconomic impacts. (Decision: TRC054) **NCPE Representative and DOM not present for this vote. Quorum was still in place** **Dacomitinib (Vizimpro ®)** *Monotherapy, for the first-line treatment of adult patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations* The committee members considered that this is a second generation tyrosine kinase inhibitor and that there are other drugs already reimbursed in the same drug class. The committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group subject to price parity (at a minimum) with the other second generation tyrosine kinase inhibitors. (Decision: TRC055) **NCPE Representative not present for this vote. Quorum was still in place** **Daratumumab (Darzalex ®)** *Daratumumab in combination with bortezomib and dexamethasone in adult patients with multiple myeloma who have received at least one prior therapy* The committee members* agreed unanimously to recommend approval of this indication to the HSE Drugs Group acknowledging that this application has already been discussed by the Drugs Group in terms of its clinical and pharmacoeconomic impacts. (Decision: TRC056)	

NCPE Representative and DOM not present for this vote. Quorum was still in place

Niraparib (Zejula ®)

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

The committee members considered that this drug:

- offers improved progression free survival to patients with relapsed ovarian cancer. This is clinically significant for this patient cohort.
- provides an option in an area of unmet need for patients with non-BRCA mutated relapsed ovarian cancer.

Having considered the clinical efficacy of the indication, the particular unmet clinical need in this patient cohort, as well as the pharmacoeconomic assessment by the NCPE, it was agreed unanimously* to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in the cost effectiveness of the drug, which is currently under negotiation.

(Decision: TRC057)

NCPE Representative not present for this vote. Quorum was still in place

Osimertinib (Tagrisso ®)

For the first-line treatment of adult patients with epidermal growth factor receptor (EGFR) mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC)

The committee members considered the clinical efficacy of the indication and the pharmacoeconomic assessment by the NCPE. The clinicians highlighted that this drug is a third generation tyrosine kinase inhibitor and offers a number of advantages over existing tyrosine kinase inhibitors; improved progression free survival and overall survival, better central nervous system penetration and better safety and tolerability profile. 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 as well as the pharmacoeconomic assessment by the NCPE, It was unanimously* agreed to recommend approval of this indication to the HSE Drugs Group subject to the NCPE caveat for improved cost effectiveness relative to other treatments, which is subject to engagement by the company.

(Decision: TRC058)

NCPE Representative not present for this vote. Quorum was still in place

Pembrolizumab (Keytruda ®)

In combination with platinum chemotherapy and pemetrexed, for the first-line treatment of metastatic, non-squamous non-small cell lung cancer in adult patients whose tumours have no EGFR or ALK positive mutations

The committee members considered the clinical efficacy of the indication and the pharmacoeconomic assessment by the NCPE. This combination offers an improved overall survival relative to existing treatments. It was noted that the eligible population is restricted to those with a performance status of 0-1. The duration of treatment beyond two years was discussed as an uncertainty but is expected to be dealt with in the negotiations with the company.

	It was agreed by majority* to recommend approval of this indication to the HSE Drugs Group in line with the NCPE recommendation that this indication be considered for reimbursement if cost effectiveness can be improved relative to existing treatments which is subject to engagement by the company. (Decision: TRC059)	
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
19/02	03/09/19	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Send 5/9/19