National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**March 26th 2019 at 5.00pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Pertuzumab (Perjeta®) Alectinib (Alecensa®)

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)	By 'phone
Dr. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr. Ronan Desmond	Consultant Haematologist, Tallaght Hospital:IHS representative	By 'phone
Mr. Shaun Flanagan	Pharmacist: HSE Corporate Pharmaceutical Unit	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	By 'phone
Dr. Deirdre O'Mahony	Medical Oncologist, Cork University Hospital: ISMO nominee	By 'phone

Non-member invited specialists present		
None		
Apologies (members)		
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: 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	By 'phone
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. No conflicts were raised during the meeting.	
2	**Notes of previous meeting and matters arising**	
	The notes of the meeting on December 5th 2018 were approved.	
3	**Drugs/Technologies for consideration**	
	Alectinib (Alecensa®) *As monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)* 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. (Decision: TRC051) **Pertuzumab (Perjeta®)** *In combination with trastuzumAB and chemotherapy for the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence* The committee noted that this had been discussed previously but that there had been an update to the clinical guidelines that warranted further discussion. The updated clinical guideline for this indication was discussed. It was noted that it had not been possible to identify a specific subcohort of patients that would benefit from this indication in the available evidence but that there was a 16% improvement in the numbers of patients achieving a pathological complete response (pCR). The clinician's view is that neo-adjuvant treatment of HER2 positive breast cancer with this indication is a standard component of the treatment paradigm for breast cancer internationally and it is important to have access for patients in Ireland. The expectation of the clinicians is that the treatment paradigm would change should this indication be reimbursed. There is an improved understanding that pCR is a relevant and clinically meaningful surrogate marker with regard to the treatment paradigm for patients with breast cancer. An increasing body of evidence supporting the correlation between improved pCR and improved overall survival (OS) generally has led to a greater desire for access amongst the clinicians. Neo-adjuvant treatment resulting in improved number of patients attaining pCR would be expected to reduce the number of patients requiring treatment with pertuzumab in the metastatic setting. From a pharmacoeconomic assessment, there is no new evidence to be considered in relation to the clinical data for this indication. It was acknowledged that the evidence was poorly presented and of poor quality as well as the lack of OS data. Having considered the input of clinicians regarding the clinical efficacy of	

	the drug regarding the need for this to be considered within the treatment paradigm for breast cancer as well as the NCPE's assessment it was agreed, by majority, to recommend approval of this indication to the HSE Drugs Group (Decision: TRC052) **Pertuzumab (Perjeta ®)** *In combination with trastuzumAB and chemotherapy for the adjuvant treatment of adult patients with HER2-positive breast cancer at high risk of recurrence* The updated clinical guideline for this indication were discussed. The benefits appear to be relatively small but there was a better response rate seen in those patients with larger tumours that were node positive and hormone receptor negative. Overall survival was assessed as a secondary endpoint and the primary interim analysis at 3 years found that there was no significant treatment effect with regard to mortality. The clinician's view is that this would be a smaller, select population as the majority of eligible patients would be treated in the neo-adjuvant setting. From a pharmacoeconomic perspective, there were some uncertainties due to the lack of clarity around the high risk population. When assumptions were changed, the resulting ICERs varied broadly, none of these were in the cost effectiveness range. There is a substantial budget impact associated with this indication. The company are yet to submit their final proposal on commercial terms so these were not available for consideration by the committee. Having considered the input of clinicians regarding the clinical efficacy of the drug regarding the need for this to be considered within the treatment paradigm for breast cancer as well as the NCPE's assessment it was agreed, by majority, to recommend approval of this indication to the HSE Drugs Group. However, this recommendation was subject to a comment by the group that the neo-adjuvant indication is more of a priority from a clinical perspective. (Decision: TRC053)	
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.	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 6.10pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
19/01	26/03/19	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Completed