National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**Feb 24th 2020 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Atezolizumab (Tecentriq®)
	Nivolumab (Opdivo®)
	Tisagenlecleucel (Kymriah®) (two indications)
	Venetoclax (Venclyxto®)

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. 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**	By 'phone
NCPE representative	National Centre for Pharmacoeconomics (NCPE) *Not present for all decisions	By 'phone
Dr. Linda Coate	Medical Oncologist, University Hospital Limerick: ISMO nominee *Not present for all decisions	By 'phone

Non-member invited specialists present		
Dr. Pamela Evans	Children's Health Ireland at Crumlin	By 'phone

Apologies (members)	
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative
Dr. Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative
Dr. Eve O'Toole	Research Group Lead, NCCP
Mr. Shaun Flanagan	Chief Pharmacist; HSE Corporate Pharmaceutical Unit
Dr. Deirdre Murray	NCCP Health Intelligence
Dr. Deirdre O'Mahony	Medical Oncologist, Bon Secour Hospital, Cork: ISMO nominee

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

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	It was noted that Prof Ray McDermott has stepped down from the group. ISMO have nominated Dr. Linda Coate as an alternative representative. Dr. Coate was welcomed to the group 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. Members will be circulated with conflict of interest forms for 2020.	
2	**Notes of previous meeting and matters arising**	
	The notes of the meeting on Nov 4th 2019 were approved subject to a clarification in the apologies for a member who was in attendance.	
3	**Drugs/Technologies for consideration**	
	Atezolizumab (Tecentriq®) *As monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) after prior platinum-containing chemotherapy* The committee members considered that this therapy was not recommended to undergo a HTA by the NCPE but noted that it would be an additional option for this patient cohort as an alternate PD-L1 inhibitor. 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: TRC065) **Nivolumab in combination with Ipilimumab (Opdivo® and Yervoy®)** *In combination with ipilimumab for the first-line treatment of adult patients with intermediate-/poor-risk advanced renal cell carcinoma* The committee members considered that this combination use is based on a large phase three trial in which the patients with intermediate/ poor-risk disease did significantly better in terms of progression free survival and overall survival. The members considered that this combination use is internationally accepted in guidelines for the treatment of this patient cohort. The HTA evaluation carried out by the NCPE recommends that this indication be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments 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: TRC066) **NCPE Representative not present for this vote. Quorum was still in place** Tisagenlecleucel **(Kymriah®)** *Paediatric and young adult patients up to 25 years of age with B -cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post -transplant*	

	or in second or later relapse As an invited expert, Dr. Pamela Evans, consultant haematologist at CHI at Crumlin outlined the clinical aspects of the use of tisagenlecleucel for this indication. CAR-T is a new type of treatment which has been described as a ground breaking advance. The safety and efficacy of this indication has been shown in a phase two, single arm trial, ELIANA as well as some other smaller trials. From a clinical perspective, there are no other options for this patient cohort other than palliation. There are associated toxicities with CAR-T but as experience with CAR-T has grown, clinicians have become more accustomed to dealing with these and there are now many protocols in place to minimise the occurrence and to detail the management of toxicity. In addition the approach to bridging chemotherapy has been refined since the trials with a reduction in intensity as patients are no longer required to be in full remission and the implementation of strict antifungal prophylaxis. From a cost effectiveness perspective, the NCPE representative detailed that there were significant challenges identified in the HTA and that there are a number of uncertainties which were considered in the scenario analyses. The committee members considered the clinical efficacy of CAR-T as well as the uncertainties and the impacts of different scenarios raised in the HTA evaluation carried out by the NCPE. It was considered that the advantages of this treatment are clinically significant for this patient cohort. Having considered the clinical efficacy of the indication and the significant advantages to this patient cohort, it was agreed by majority to recommend approval of this indication to the HSE Drugs Group subject to financial discussion with the company and a consideration of the potential for collection of data on outcomes. (Decision: TRC067) **Dr. L. Coate not present for this vote. Quorum was still in place** Tisagenlecleucel **(Kymriah ®)** *Adult patients with relapsed or refractory diffuse large B -cell lymphoma (DLBCL) after two or more lines of systemic therapy* As above, it was considered by the members that CAR-T is a new type of treatment which has been described as a ground breaking advance. The safety and efficacy of this indication has been shown in a phase two, single arm trial, JULIET. From a clinical perspective, there are few other options for this patient cohort. There are associated toxicities with CAR-T but similarly to the paediatric setting, as experience with CAR-T has grown, the potential side effects are now well known to clinicians and there are management protocols in place to minimise these and to detail the management of toxicity. From a cost effectiveness perspective, the NCPE representative detailed that there were also significant challenges identified in the HTA evaluation process for this indication. There are a number of uncertainties which were considered in the scenario analyses. The committee members considered the clinical efficacy of CAR-T as well as the uncertainties and the impacts of different scenarios raised in the HTA evaluation carried out by the NCPE. It was considered that the advantages of this treatment are clinically significant for this patient cohort. Having considered the clinical efficacy of the indication and the significant advantages to this patient cohort, it was agreed by majority to recommend	

	approval of this indication to the HSE Drugs Group subject to financial discussion with the company. (Decision: TRC068) **Dr. L. Coate not present for this vote. Quorum was still in place** **Venetoclax (Venclyxto ®)** *In combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy* The committee members considered the clinical efficacy of this indication as seen in a phase three trial and considered that this combination in this patient cohort offers no unexpected additional toxicity and an improved outcome for patients. This is a defined period of treatment for two years which was considered in line with the trial and is detailed in the NCPE HTA evaluation. The NCPE recommends that venetoclax (Venclyxto®) be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments Having considered the clinical efficacy of the indication and the NCPE recommendation, it was agreed unanimously to recommend approval of this indication to the HSE Drugs Group. (Decision: TRC069) **NCPE Representative not present for this vote. Quorum was still in place**	
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 for March / April.	
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
20/01	24/02/2020	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	