National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**April 26th 2021 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Acalabrutinib (Calquence®)
	Nivolumab (Opdivo®)
	Polatuzumab (Polivy®)
	Trastuzumab emtansine (Kadcyla®)

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 University Hospital: IHS representative	By 'phone
Dr. Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative	By 'phone
Ms. Patricia Heckmann	NCCP AND **- Chair**	By 'phone
Prof. Michaela Higgins	Medical Oncologist, St. Vincent's University Hospital: ISMO nominee	By 'phone
Dr. Susan Spillane	HTA Directorate: HIQA nominee	By 'phone

Non-member invited specialists present

Apologies (members)	
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative
Dr. Linda Coate	Medical Oncologist, University Hospital Limerick: ISMO nominee
Ms. Ellen McGrath	Chief Pharmacist; HSE Corporate Pharmaceutical Unit
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee

Observers present
None

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded of the confidentiality of documentation and discussions. Reminder to any who have not yet returned a recent COI form to please do so. 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 March 29th were approved.	
3	**Drugs/Technologies for consideration**	
	Acalabrutinib (Calquence®) (Ref. TRC 089) • *For the treatment of previously untreated CLL in the presence of 17p deletion or TP53 mutation in adult patients unsuitable for chemoimmunotherapy* • *For the treatment of adult patients with CLL who have received at least one* It was discussed that this indication was not recommended for a full HTA as it represents a sub-set of the currently licensed indication and there is another agent reimbursed for this subset. There is no head to head comparator with the other medicine currently available but the Elevate-RR study is anticipated to be published which will consider if this medicine is non-inferior. The clinical aspect of this indication was discussed, noting that there is a desire to have this treatment option available for patients as there are some differences in the toxicity profile, therefore this medicine may be more suitable for certain patient cohorts. This application for reimbursement is being progressed as a cost minimisation piece by the PCRS as an alternate agent in this indication. The committee members unanimously recommended approval for reimbursement noting that it will not be subject to a HTA and subject to cost minimisation. The TRC asked that the company be requested to submit the data from the Elevate –RR study to the HSE CPU once that is available. *(Decision:TRC 089)* *OB was not present for this vote, quorum was still in place* **Nivolumab (Keytruda®) (Ref. TRC 090)** *As monotherapy is indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine and platinum-based combination chemotherapy* It was noted that there is a high unmet need for this patient cohort. From the pharmacoeconomic considerations, it was discussed that this indication was not recommended for a full HTA. The supporting evidence is a phase 3 study, ATTRACTION-3, comprising of mostly Asian population. The study showed a small improvement in median overall survival of <3months The EMA	NCCP to communicate recommendations to HSE Drugs Group.

considered at length the generalisability of the evidence to a western EU population and concluded that the likely benefit may be less than that identified in the trial, but approved the indication. It was noted that negative outcomes was reported in a similar indication for an alternate immunotherapy, where the patient population comprised of more western Caucasians.

The clinical aspects of this indication were discussed, noting that there is a clear unmet need in the patient population who have very poor prognosis. It was outlined that this medicine is showing a modest gain in trials ongoing in adjuvant disease and that is a strong indicator of anticipated benefit and activity in this indication, where patient numbers are expected to be small.

Having considered the clinical efficacy of the indication and the unmet need, the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness.

(Decision:TRC 090)

Polatuzumab (Polivy®) (Ref. TRC 091)

In combination with bendamustine and rituximab for the treatment of adult patients with relapsed/ refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant

The key points of the NCPE's HTA assessment were outlined, noting that the NCPE had recommended this be reimbursed, subject to an improvement in cost effectiveness. This considered that there was uncertainty associated with the standard of care in the patient population, and that there is a significant budget impact associated with this application.

The clinical benefits were detailed, including that there are few options for this patient population, and that is a contributory factor to the lack of an accepted standard of care for this cohort. It was discussed that clinicians are familiar with this drug class in terms of management of toxicities. The clinicians would welcome this drug as an option to treat this cohort of patients where there are limited options currently and therefore a clear unmet need.

Having considered the clinical efficacy of the indication, the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness

Trastuzumab emtansine (Kadcyla®) (Ref. TRC 092)

A monotherapy, is indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy

This is a treatment for Her2positive early breast cancer patients, who are currently treated with trastuzumab, noting that there are biosimilar trastuzumab options available. From the HTA assessment, it was discussed that the main uncertainty is the immaturity of the outcomes data, with a relatively small number of events after 41months follow up. From a safety consideration, this medicine is associated with a decreased quality of life and some increased safety risks but there is a benefit in invasive disease free survival and overall survival. The ICERs were outlined, which are within the cost effectiveness parameters but there is a large budget impact due to the

	large patient numbers. Clinically it was discussed that this is a very clinically effective drug, and that there is a strong desire from the clinicians to have this option available for this patient cohort as it represents an opportunity to cure/ prevent recurrence in 50% of patients with residual disease after initial treatment. It was noted that this is approved in many other jurisdictions as a standard of care for this patient cohort. It was noted that DCIS was excluded in the trial. Having considered the clinical efficacy of the indication, the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness	
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 May 24th 2021	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 5.30pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
21/04	26.4.2021	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Complete