National Cancer Control Programme

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**24th October 2022 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Mogamulizumab Poteligeo®
	Nivolumab Opdivo®
	Tafasitamab Minjuvi®

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 Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative	By 'phone
Prof Michaela Higgins	Medical Oncologist, St. Vincent's University Hospital: ISMO nominee	By 'phone
Ms Patricia Heckmann	NCCP AND - Chair	By 'phone
Ms Fiona Mulligan	PCRS representative	By 'phone
Dr Jarushka Naidoo	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	By 'phone
Dr Derville O'Shea	Consultant Haematologist, Cork University Hospital: IHS representative	By 'phone
Susan Spillane	HTA Directorate: HIQA nominee	By 'phone
Non-member invited specialists present		

Apologies (members)	
Dr Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee
Dr Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative
Observers present	
Ms AnneMarie De Frein	Chief 1 Pharmacist, NCCP
Ms Helena Desmond	Senior Pharmacist, NCCP

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded 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 August 29th 2022 were agreed.	
3	**Drugs/Technologies for consideration**	
	Mogamulizumab Poteligeo® **(Ref. TRC 121)** *As monotherapy for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.* The clinical aspects of this indication were discussed. The supporting evidence for this indication is the phase MAVORIC III study, which evaluated the safety and efficacy of mogamulizumab compared to vorinostat in the treatment of patients with MF or SS, noting that vorinostat is not licensed by the European Medicines Agency and is not used in Irish clinical practice. The study showed a progression free survival (PFS) advantage with 7.7 months in mogamulizumab arm versus 3.1 months on vorinostat arm. From a clinical perspective, there is a desire among the clinicians to have this treatment available, highlighting that there are currently limited treatments options in this space and a clear unmet clinical need. The safety profile was discussed; the side effects are reasonably well tolerated, although there are toxicities, most notes being infusion reactions and skin rashes. The pharmacoeconomic aspects as outlined in the HTA assessment carried out by the NCPE were discussed. It was noted that for this patient cohort there is no single standard of care. It was outlined that the application for reimbursement is for patients who have received at least one prior systemic therapy this sub-population is narrower than the licensed indication, which includes all patients with MF and SS. This aligns to the approvals seen from NICE. The cost effectiveness assessment was outlined for this sub-population, noting the requirement for complex modelling and flagging a number of uncertainties and limitations as detailed in the HTA, including a number of scenario analyses. Treatment with mogamulizuamab is associated with high cost and high ICERS. The NCPE review group made a number of adjustments to the applicant's base case and concluded that a significant total price discount is required to meet the willingness to pay threshold of €45k/QALY. NCPE review group recommended that mogamulizumab not be considered for reimbursement unless cost can be improved relevant to existing treatments. Commercial negotiations with the company are ongoing. Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost. *(Decision:TRC121)*	

Nivolumab Opdivo® **(Ref. TRC 122)**

Nivolumab in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma

The clinical aspects of this indication were discussed. The supporting evidence for this indication is the phase III CheckMate-743 study which evaluated the efficacy and safety of nivolumab in combination with ipilimumab versus standard of care (SOC) chemotherapy (pemetrexed + CISplatin or CARBOplatin) in previously untreated patients with malignant pleural mesothelioma (MPM). This study has 3-year survival data, and has demonstrated a benefit in overall survival (OS) with a hazard ratio (HR) of 0.73, and a median OS of 18.1months in the nivolumab/ipilimumab arm vs 14.1 months in the SOC Arm. It was discussed that there are a number of histological subtypes and that epithelioid is more predominant in Ireland. From the subgroup, analysis in the trial the benefit appears to be driven by the non-epithelioid subtypes, which is the more clinically aggressive, with a HR of 0.46, but there was still a benefit in the epithelioid subtype, with a HR of 0.86. The study showed a benefit in all comers regardless of histology and is considered internationally as a new SOC for MPM. It was highlighted that the approval for nivolumab in combination with ipilimumab in this indication represents the first approval of a new treatment with a clear benefit in treating MPM since 2004. There is a strong desire among the clinicians to have this treatment option available for first line treatment for MPM in line with international guidelines, noting that the cohort of patient requiring treatment is quite small.

The pharmacoeconomic aspects as outlined in the HTA assessment carried out by the NCPE were discussed. The anticipated place in therapy is in line with the licensed indication. A number of adjustment to the model were carried out including to account for the different histology subtypes, however it was highlighted that the use of nivolumab and ipilimumab in MPM demonstrated a clinical benefit. The safety profile was discussed with no new concerns were identified. This treatment is associated with significant cost, with an estimated budget impact (BI) of [redacted] over 5 years. The ICERS were noted to be considerably higher than the willingness to pay threshold.The recommendation of the review group was to recommend reimbursement subject to an improvement in price. Commercial negotiations with the company are ongoing.

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

(Decision:TRC122)

Tafasitamab Minjuvi ® **(TRC 123)**

In combination with lenalidomide followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

The Rapid review (RR) carried out by the NCPE for this indication recommend a full HTA, which has not been submitted to date. It was noted that there are a number of approved treatments already in this space as comparison treatments. Commercial negotiations with the company are ongoing to determine if this application could progress on a cost minimisation basis. If this is not achievable, then a full HTA may be required to be submitted. Should a full HTA be submitted for consideration, this indication may be brought back to this committee for further discussion.

	The clinical aspects of this indication were discussed. The supporting evidence for this indication is the phase II study, L-MIND with evaluated the safety and efficacy tafasitamab in combination with lenalidomide of in adult patients with relapsed or refractory (R/R) DLBCL after 1 to 3 prior systemic DLBCL therapies. It was discussed that although there is a lack of head to head data for tafasitamab in combination with lenalidomide against the current standards of care, early indicators suggest that it is an effective treatment. It was discussed that the cost appears to be higher than the current standard of care. The clinicians acknowledged that the quality of evidence is not very high but that this level of evidence has supported other treatment approved for reimbursement for this patient cohort. There is a desire to have this option available for the treatment of patients. Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost. *(Decision:TRC122)* *One member was absence from voting, however quorum was in place*	
4	**Update on other drugs in the reimbursement process**	
	An update had been shared with the group in the documentation for the meeting	
5	**Next meeting**	
	The proposed date for the next meeting is November 28th	
6	**Any other business / Next meeting**	
	Patricia Heckmann announced that she will be stepping down as Chair of the committee. The members thanked Patricia for her stewardship, noting her commitment for many years to the role. The NCCP National Director has appointed Ms AnneMarie De Frein as her replacement.	
	Term of reference is currently under review and will be circulated for comment prior to the next meeting	NCCP

The meeting concluded at 5.50pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
22/07	24.10.2022	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Competed
22/07	24.10.2022	NCCP to circulate the revised Term of reference to the committee for comment.	NCCP	Competed