National Cancer Control Programme

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**28th November 2022 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Fedratinib (Inrebic®)
	Niraparib (Zejula®)
	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)	By 'phone
Dr Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Ms AnneMarie De Frein	NCCP Chief I Pharmacist – Chair	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
Susan Spillane	HTA Directorate: HIQA nominee	By 'phone
Non-member invited specialists present		
Apologies (members)		
Prof Michaela Higgins	Medical Oncologist, St. Vincent's University Hospital: ISMO nominee	
Ms Ellen McGrath	PCRS representative	
Dr Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	
Observers present		
Ms Patricia Heckmann	AND NCCP	By 'phone
Ms Helena Desmond	Senior Pharmacist, NCCP	By 'phone
Dr Derville O'Shea	Consultant Haematologist, Cork University Hospital: IHS representative	By 'phone

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 October 24th 2022 were agreed.	
3	**Drugs/Technologies for consideration**	
	Fedratinib (Inrebic®) (**Ref. TRC 124)** *For the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (MF), post polycythaemia vera myelofibrosis (PVMF) or post essential thrombocythaemia myelofibrosis (ET MF) who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.* This indication was not discussed in detail as it was outlined that this has already been discussed at HSE Drugs group and it is expected to be progressed on a cost minimisation basis. There is a desire from the clinicians to have this treatment option available for this patient cohort. The committee members agreed unanimously to recommend approval of this indication. *(Decision:TRC124)* Pembrolizumab (Keytruda®) (**Ref. TRC 125)** *First-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.* The clinical aspects of this indication were discussed, noting that pembrolizumab is currently reimbursed for many different cancer treatment indications and clinicians are very familiar with this drug and its management. In metastatic colorectal cancer MSI-H appears to affect a relatively small cohort of patients of approx. 5%. In the Keynote 177 trial, an improved progression free survival was seen in the pembrolizumab arm, when compared to the chemotherapy standard of care (SOC) arm. The safety profile was discussed, and it was noted that pembrolizumab showed a favourable safety profile when compared to the SOC, and noting that clinicians are familiar with pembrolizumab toxicity management. There is a strong desire among clinicians to have this treatment option available to this patient cohort. The health technology assessment was outlined by the NCPE representative. The KEYNOTE 177 study is a phase III study which evaluated the efficacy and safety of pembrolizumab versus SOC chemotherapy (5-fluorouracil (5-FU) based therapy with or without bevacizumab or cetuximab) in the first line treatment of adult patients with dMMR or MSI-H metastatic colorectal cancer. The co-primary end points were progression free survival (PFS) and overall survival (OS). The study demonstrated that there was a clear benefit seen with a statistically significant benefit in the median PFS of 16.5 months in the pembrolizumab arm vs 8. 2 months in the SOC arm, however there was no statistically significant OS benefit for pembrolizumab. The pharmacoeconomic aspects as outlined in the NCPE review group's assessment were discussed, including the modelling and the adjustments made to the base case. The ICERS were outlined for three scenarios at list price. For pembrolizumab vs SOC, the ICER was €48,777 per QALY, vs mFOLOX 6 + panitumumab the ICER was €41,040 per QALY and vs XELOX the ICER was €60,889, with the probability of pembrolizumab being cost	

	effectiveness was 14% at the €45,000 per QALY threshold. The applicant [redacted] were also outlined. The budget impact (BI) was outlined, estimating that 47 pts will eligible for treatment in year 1 increasing to 51 by year 5. The estimated 5 year gross BI at the list price is €35.55 million including VAT and 5-year net budget was estimated to be €29.4 million including VAT. The recommendation of the NCPE review group was to recommend reimbursement if the PAS offer is met. [redacted] [redacted] Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost. *(Decision:TRC125)* **Niraparib Zejula®** *First-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.* Discussion of this item was deferred and will be added to the agenda for the next meeting.	
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 January 23rd 2023	
6	**Any other business / Next meeting**	
	Term of reference reviewed and agreed with minor changes. The revised Terms of Reference will be finalised circulated prior to the next meeting	NCCP

The meeting concluded at 5.15pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
22/08	28.11.2022	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Completed
22/08	28.11.2022	Circulate finalised revised Terms of Reference	NCCP	Completed