Appendix Six – IFR Panel Decision Framework Document

INDIVIDUAL FUNDING REQUEST PANEL DECISION FRAMEWORK DOCUMENT (DFD)
Notes:

1. A copy of this form is provided to each Panel member for each Panel case.
2. The copies will, at the end of the meeting, be collected by the IFR Team.
3. Those copies will then be used to produce one summary DFD. That summary will give reasons for the decision at each stage of the process.
4. Individual Panel member forms will not be retained.
5. The summary DFD will be used to record the key points discussed by the IFR Panel and the views of the IFR Panel.
6. The summary DFD will be shared with the applicant as an enclosure with the outcome letter from the IFR Panel and signed off by the senior clinical member of the Panel and the Panel Chair.

Panel meeting date:	**6 March 2019**			
Request reference:	**NHSE-97177683**			
Panel Membership	**Name**	**Designation**	**Declaration of interest**	**Decision**
	[redacted]	Chair	None	**Unanimously declined**
	[redacted]	Clinical Director	None	
	[redacted]	Specialist in Public Health	None	
	[redacted]	Pharmacy Lead	None	
	[redacted]	Programme of Care Lead	None	
	[redacted]	Programme of Care Lead	None	
	[redacted]	Patient & Public Voice	None	
	[redacted]	Clinical Member	None	
	[redacted]	Clinical Member	None	
	[redacted]	IFR Case Manager		
	[redacted]	IFR/CDF Lead		
	[redacted]	IFR Administrator		
	[redacted]	IFR Senior Manager		

	[redacted]	Head of Clinical Effectiveness	
Intervention Requested:	**Ipilimumab and pembrolizumab to treat metastatic squamous cell cancer of skin**		

No.	Points for decision	Discussion notes	Decision
Individual Need for Care			**Yes/No**
1.1	Does NHS England have a clinical commissioning policy and/or is there NICE TA/HST guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient **AND** Is this patient outside the access criteria for treatment under that policy/guidance, where applicable? *If Yes, there is a policy/guidance and the patient is outside it, record and go to question 2.1.* *In any other case, go to question 1.2, below.*	The IFR Panel agreed there is no clinical commissioning policy or NICE TA/HST guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient.	**No**
1.2	There is no NHS England clinical commissioning policy or NICE TA/HST guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient **AND** The intervention is not routinely funded? *If there is no policy/NICE guidance and the intervention is not routinely funded, record, and go to question 2.2.* *In any other case, the application is outside the scope of the policy, record and go to question 5.*	The IFR Panel noted there is no NHS England clinical commissioning policy or NICE TA/HST guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient. The requested intervention is not routinely funded.	**Yes**

Evidence of clinical effectiveness and exceptionality			Yes/No
2.1	If the answer was Yes to question 1.1: Does the evidence included within the application demonstrate that the patient is in a different clinical condition when compared to the typical patient population with the same condition **AND** (if relevant) at the same stage of progression **AND** that **because of that difference** the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient? Guidance for Panel: In answering this question, have regard to the guidance on clinical exceptionality in the IFR policy (section 4, page 8-9). *If Yes, record and go to question 3.1.* *In any other case, record and go to question 5.*	N/A	**N/A**

2.2	If the conditions in question 1.2 were satisfied: Is the patient's clinical presentation so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken? Guidance for Panel: To understand what is meant by "so unusual", have regard to the guidance on clinical exceptionality in the IFR policy (section 4, page 9). *If Yes, record, and go to question 3.1.* *In any other case, record and go to question 5.*	The IFR Panel discussed the condition metastatic squamous cell carcinoma of the skin. The IFR Panel discussed the incidence of the condition. The IFR Panel agreed that the incidence figures in the supporting evidence submitted with the IFR application form do not correlate with the rarity stated in the application. The request form indicated an incidence of diagnosis of "this specific condition" at one per million. The IFR Panel regard the "specific condition" as metastatic squamous cell carcinoma and the supporting evidence suggests a larger group of patients exist with metastatic squamous cell carcinoma of the skin (15- 35 per 100,000 with 5% metastasising or recurring). The IFR Panel agreed that this patient belongs to a group of patients with the condition metastatic squamous cell carcinoma of the skin who failed or who could not tolerate standard therapies. The IFR Panel agreed that this patient is severely affected by the disease, but this would correlate with the natural disease progression of this condition. The IFR Panel noted that there is no published evidence to support use of the requested combination of drugs for this condition and that evidence for these drugs being the most active agents came from one clinical opinion. The IFR Panel discussed the factors in the application that made a case for exceptionality: 1. That the patient has already been able to access the combination of drugs requested by self-funding treatment. The IFR Panel referred to and discussed the Commissioning Policy: Ethical framework for priority setting and resource allocation (https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf), in particular the core principles (p6-7). Core principle 2 states *'a commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal need to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. The NHS CB considers that if funding for a*	**No**

		treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory.' Core principle 4 states '*Commissioners are frequently asked to take on funding commitments made by another statutory body or other type of organisation (including pharmaceutical companies, research bodies or acute trusts) or indeed an individual who has funded the treatment themselves. The NHS CB, like any other organisation, cannot assume responsibility for a funding decision in which it played no part unless there is a legal requirement to do so.'* Therefore, the IFR Panel agreed that preferential treatment cannot be given to an individual who is part of a group of patients with the same clinical need, unless they are able to clinically differentiate that patient from the rest of the group. The IFR Panel also agreed that this patient could not be differentiated from the group of patients with the condition metastatic squamous cell carcinoma of the skin who failed or who could not tolerate standard therapies. 2. That this patient is younger than the average age for patients with this condition. The IFR Panel discussed the average age of patients with the condition metastatic squamous cell carcinoma of the skin, as detailed in the clinical papers provided as part of the application. The IFR Panel agreed that an average age will always include a range of values, and that the patient fell within these values.	

Experimental and Unproven treatment			**Yes / No**
3.1	Is this treatment experimental [or unproven] (as defined in section 34, pages 15-16)? *If Yes, record and go to question 3.2.* *If No, record and go to question 3.3.*	N/A	**N/A**
3.2	If the treatment is experimental [or unproven] as per question 3.1, what is the Panel's assessment of the following in relation to the submitted evidence of effectiveness (sections 39- 40, pages 16-17): a) The potential benefit and risks of treatment; AND b) The biological plausibility of benefit based on other evidence; AND c) The estimated cost of the treatment and anticipated value for money; AND d) The priority of the patient's needs compared to other competing needs and unfunded developments?	N/A	**N/A**

	Will funding the treatment contribute to the knowledge base relevant to treatment of the condition in question? Is it appropriate to consider funding through an IFR rather than research funding? *If the assessment of factors a-d above is satisfactory and the two questions set out above are answered positively, record and go to question 4.* Guidance for Panel: keep in mind the additional requirements that the IFR policy applies to evaluating both clinical efficacy and the use of NHS resources when a treatment is experimental or unproven, see in particular paragraph 32 of the IFR policy. *In any other case, record and go to question 5.*		
3.3	If the treatment is *not* experimental and/or unproven as per question 3.1: Is there sufficient evidence to show that the proposed treatment is likely to be clinically effective in this individual case? Guidance for Panel: In answering this question have regard to the guidance on clinical effectiveness in the IFR policy (sections 23-25, page 13-14). *If Yes, record and go to question 4.* *In any other case, record and go to question 5.*	N/A	**N/A**

Good use of NHS resources and affordability			Yes/No
4.	**Consider as a minimum:** a) What are the absolute costs involved in funding this treatment, considering cost and time receiving treatment? b) Is this cost one-off or is there a need for recurrent funding? c) What benefit can the patient expect to receive and for how long? d) How certain are costs and benefits? Guidance for Panel (sections 27-29, pages 14-15): As uncertainty increases, the likelihood of the anticipated benefits being realised decreases. e) Is there another source of funding known to be available or that could be available, for example industry funding for those who have taken part in clinical trials? f) Taking these and any other factors considered relevant into account, does the Panel consider that use of this drug/intervention in this individual case is a good and equitable use of NHS resources? *Record the answers and go to question 5.*	N/A	**N/A**

Equalities			Yes/No
5	Guidance for Panel (sections 19-22, pages 12-13): In general issues of equality and diversity are addressed in clinical policy development (see question 6). Considering only clinical factors, does the application raise any clinically relevant equality concerns that have not already been considered above? Is the fact that the applicant has a particular protected characteristic (age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief, sex; sexual orientation) clinically relevant to the application? Would allowing or refusing the application represent an opportunity to eliminate discrimination or to advance equality of opportunity, or to reduce health inequalities? *If Yes, review the decision in light of these concerns, if they have not been discussed and recorded earlier. Be willing to reach a different decision if you consider that appropriate, and record that review.* *If No or after review, go to 'RECORD OF DECISION' below.* *Additionally, consider question 6, although this is not part of the consideration of the IFR.*	The application does not raise any clinically relevant equality concerns that have not already been considered within the application.	**No**

Policy developments			Yes / No
6	Has this case brought to light any issues which should be referred on within NHSE to inform policy development? If so refer them to [ ]		No

RECORD OF DECISION	SUMMARY
Funding Approved: No Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requester. Include any conditions, outcome measures to be monitored and review mechanisms required. Date of review: N/A	N/A
Funding Declined: Yes Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requester.	The IFR Panel agreed that this patient belongs to a group of patients with the condition metastatic squamous cell carcinoma of the skin who failed or who could not tolerate standard therapies. The IFR Panel agreed that this patient may be slightly younger than the average age for patients with this condition; however, they noted they are not significantly younger than the range of ages for this condition. Having considered the Commissioning Policy: Ethical framework for priority setting and resource allocation, the IFR Panel agreed that preferential treatment cannot be given to an individual who is part of a group of patients with the same clinical need, unless they are able to clinically differentiate that patient from the rest of the group. The IFR Panel agreed that this patient could not be differentiated from the group of patients with the condition metastatic squamous cell carcinoma of the skin who failed or who could not tolerate standard therapies. Therefore, the NHS cannot assume responsibility for a funding decision in which it played no part for one individual who belongs to a larger group of patients in the same clinical situation as this would be discriminatory.

RETURN THIS FORM TO THE PANEL ADMINISTRATOR AFTER THE MEETING