

Individual Funding Request Policy

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Name of author and title:	Dr Mike Caley, ICB Deputy Medical Director, and Lucy Dyde, IFR Manager
Name of reviewer and title:	Angela Brady, Chief Medical Officer
Department:	Medical Directorate

VERSION HISTORY

VERSION F	ISTORT		Consulting and Endorsing
Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
April 2023	V2	 Formatting changes Amendment: reference to Arden Commissioning Support Unit removed Update to IFR panel membership; NEM replaced with Chief Medical Officer or a deputy Reference to "GPs" replaced with "Clinicians" to enable a wider pool of clinicians to attend Addition of allowance of audio evidence from the patient Pronouns removed Update to IFR Review panel membership: "Clinical member of ICB Board" replaced with "Another ICB Executive Officer (the Chief Delivery and Performance Officer being the usual first choice)" 	

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1. Introduction

- 1.1. Individual Funding Requests may be received by NHS Coventry and Warwickshire Integrated Care Board ("the ICB") at any time but need to be considered within the overall commissioning framework in order not to distort pre-existing priorities.
- 1.2. An Individual Funding Request ("IFR") is a request received from a clinician which seeks funding for a single identified patient for a specific treatment on the basis that the patient has exceptional clinical circumstances. IFRs will only be accepted from a clinician on behalf of a patient.
- 1.3. The patient must be suffering from a medical condition for which the ICB has commissioning responsibility 1 and either the ICB has no commissioning policy in respect of the treatment for which funding is sought, the patient does not fulfil the criteria for eligibility for treatment set out in the policy or the ICB has a policy stating that it will not routinely fund the drug or intervention for any patient.
- 1.4. The ICB's IFR Panel will only consider allocating funding for the treatment for the specific patient, on whose behalf the IFR is submitted, if it can be demonstrated that the patient's clinical circumstances are exceptional when compared to other patients with the same presenting medical condition at the same stage of progression ("the cohort patients"). Specifically, the IFR Panel may consider, based upon the evidence provided to it, whether or not it has been demonstrated that the patient would, in all likelihood, benefit significantly more from the treatment than the cohort patients.

1.5. Service Development

The IFR should not constitute a request for a service development. Where a clinician feels that a treatment would benefit a group of patients who all share similar clinical circumstances, the clinician should contact the secondary care trust's management team with a view to submitting a business case for consideration by the ICB. Likewise, the ICB does not expect the IFR process to be utilised to provide funding for patients to continue to receive treatment commenced as part of a clinical trial. In accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, responsibility lies with those conducting the trial to ensure a clear exit strategy.

1.6. Commencing Treatment prior to Approval

When an IFR is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the ICB will approve funding, that decision is a clear risk taken by the trust. In considering the request for funding, the ICB will apply the criteria set out in this policy just as it would for any other request, with no presumption in favour of the patient continuing the treatment at the ICB's expense. If a clinician decides to provide a treatment/drug at risk and retrospectively completes an IFR proforma then the IFR must be submitted within one month of the procedure/administration of the drug taking place. Retrospective funding will not routinely be supported apart from where a submission is made within one month of the procedure/administration of the drug, where funding, if approved, will be backdated to the commencement of treatment.

1.7. Moving from another ICB

Where patients in receipt of a package of care or treatment option approved by another ICB move into the ICB's area and become the responsibility of the ICB, the ICB's policy is that, subject to resource constraints, the ICB will continue to fund the treatment, provided that the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate.

1 commissioned centrally by Specialised Services.

2. Individual Funding Requests Process for the Consideration of Cases

- 2.1. The IFR process is managed on behalf of the ICB by the IFR Team.
- 2.2. There are three tiers to the ordinary IFR process

Tier 1: Initial Submission

Where a clinician wishes to make a referral or apply for funding for a treatment or therapy which may fall within the remit of the IFR policy, the following process should be followed:

Initial Discussion with the IFR Team Manager/IFR Team

I. If the clinician is in any doubt, the IFR Team Manager/IFR Team will be able to advise, with the support of the relevant commissioning/contract managers, if required, whether the proposed referral/treatment would be covered by our existing portfolio of Service Level Agreements or current commissioning policies. If it would not be, the IFR Team Manager /Team may be able to suggest an alternative that will meet the patient's clinical needs. Neither the IFR Team Manager nor the IFR team have the authority to approve referrals outside existing pathways, whatever the individual patient's personal circumstances. In such cases an IFR should be submitted.

Submission of IFR Pro-forma

- I. All IFRs must be submitted on the ICB approved IFR pro-forma (see **Appendix 1**) in type-written/word processed format (i.e. not handwritten). It is the responsibility of the requesting clinician through the requesting organisation's management team to ensure that all information relevant to the evaluation of the request is submitted.
- II. Pages 1 and 2 of the pro-forma should be referred to for further detailed instructions with regard to completing it. The IFR Team will acknowledge submission of an IFR.
- III. For requests received where the IFR pro-forma has not been used, the IFR team will ask the requesting organisation/clinician to complete the pro-forma.
- IV. If the pro-forma is not returned within 6 weeks, the request will be treated as withdrawn.
- V. Incomplete pro-formas or pro-formas requiring clarification will be returned to the requesting organisation/clinician for proper completion, clarification or the provision of additional information.
- VI. If information is required from third parties, written consent shall be obtained from the patient before such information is sought.

Triage of IFR Pro-forma

- I. The IFR Team will review all IFR pro-formas and advise the requesting organisation/clinician in case where the patient clearly falls within the criteria set out in a commissioning policy and whose treatment will therefore be routinely funded.
- II. In relation to requests where there is no commissioning policy or where the patient clearly falls outside the funding criteria set out in the commissioning policy, the request may be considered as a potential service development, in which case it should be considered against competing priorities in the annual commissioning round, or the request can potentially be considered on grounds of exceptionality. In both these cases submission will need to be made to the ICB's IFR Panel.
 - III. A service development is any aspect of healthcare which the ICB has not historically

agreed to fund and which will require additional and predictable recurrent funding. A request for treatment will be classified as a request for a service development if there are likely to be a cohort of similar patients:

- who are in the same or similar clinical circumstances as the patient on whose behalf the request is made;
- whose clinical condition means that they could make a -the same or a similar request (regardless as to whether or not such a request has in fact been made); and
- who could reasonably be expected to benefit from the requested treatment to the same or a similar degree.

Service developments include, but are not limited to:

- New services;
- New treatments, including medicines, surgical procedures and medical devices; New diagnostic tests and investigations;
- Quality improvements; and
- Requests to vary an existing policy, for example, to add an indication for treatment, expand access to a particular patient sub-group or lower the threshold for treatment.
- IV. If a request, once considered by the IFR Panel, is considered to be a service development, a response will be made to the requesting organisation/clinician, who may be invited to develop a business case for consideration by the ICB, if appropriate.

Tier Two: Individual Funding Requests Panel

Preparing a case for the Individual Funding Requests Panel

- I. Once a fully completed IFR pro-forma is received from the clinician, the IFR Team will write to the clinician and patient (when appropriate) to advise of the date of the IFR Panel. A patient leaflet will be sent with the pre-panel letter to the patient, explaining the operation of the IFR process and to give the patient the opportunity to provide any written/audio evidence which the patient would wish the IFR Panel to take into consideration in reaching its decision as to whether or not the patient has exceptional clinical circumstances. This might include the patient's understanding of the evidence base and how this might apply to the patient and information from clinicians or patient support groups, etc. Non-clinical social factors will not be taken into account.
- II. The IFR Team may also write to other health professionals with clinical involvement in the patient's care (for example consultant, GP, therapist etc.) for clarification of the patient's needs, evidence base etc, if appropriate and subject to the patient's consent being obtained.
- III. The IFR Team, with support from Public Health and Medicines Management, where appropriate, will produce a summary of the case for the information of the IFR Panel (see Appendix 2). Additional information may be required and will be requested from parties involved in the case, as appropriate. This summary will be included with the IFR Panel papers prepared and provided to IFR Panel members by the IFR team.
 - IV. The IFR Panel will determine all matters within its Terms of Reference ("ToR") (see Appendix 3).

Tier Three: Individual Funding Requests Review Panel

- I. A request for a review should be made in writing to the ICB's Accountable Officer within three months of the original IFR Panel decision. This time limit may be extended, in appropriate circumstances, at the discretion of the Accountable Officer.
- II. A request to the IFR Review Panel can be made by the individual patient affected by the decision or by a carer, a parent/guardian or a clinician on behalf of that individual. Such a request may only be made on the ground that due process was not followed by the IFR Panel in reaching its original decision.
- III. The IFR Review Panel will review the process that the IFR Panel followed rather than the decision that was reached. If the IFR Review Panel believes that the correct process was not followed, then it will instruct the IFR Panel to consider the case again.
- IV. The IFR Team will support the process and ensure that reviews are presented to the ICB's IFR Review Panel for consideration as expeditiously as possible.
- V. The IFR Review Panel will determine all matters within its ToR (see Appendix 4).

3. Urgent Decisions

- 3.1. There may be occasions when an urgent decision needs to be made before the IFR Panel can be convened. An IFR will be handled as urgent where, considering the nature and severity of the patient's clinical condition, a patient faces a substantial risk of significant harm if a decision is not made before the next scheduled IFR Panel meeting. It is expected that only a small minority of IFRs will be urgent and these will usually involve life-threatening conditions.
- 3.2. Urgency cannot arise as a result of a failure by a clinician to expeditiously submit an IFR pro- forma in the usual way.
- 3.3. Where an urgent IFR request is received from a clinician, the IFR Team will assess the request to ensure that sufficient information is available for the IFR Panel to make a decision without compromising any of the principles upon which decisions should be made.
- 3.4. The IFR Team will be responsible for distributing the information/evidence received from the requesting clinician electronically to IFR Panel members. The IFR Team will also be responsible for communicating the IFR Panel's decision back to the requesting clinician.
- 3.5. The urgent decision will be made by virtual discussion via email or phone between the IFR Panel members.
- 3.6. The IFR Panel shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process

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Appendix 1 - Individual Funding Request Pro-forma

GENERAL GUIDANCE - PLEASE READ PRIOR TO COMPLETING THIS PROFORMA

Applications need to include the following information and be completed as follows:

1. This pro-forma is to be completed by clinicians acting on behalf of their patient to request funding from the ICB for individual funding of drugs or other interventions not routinely commissioned by the ICB.

The following should be provided:

- A comprehensive and balanced clinical picture of the history and present state of the patient's medical condition.
- The nature of the treatment requested and the anticipated benefits of the treatment.
- The degree of confidence of the Clinical Team that the outcomes will be delivered for this
 particular patient.
- Previous treatments/interventions this patient has received for this condition and the outcome of these for the patient.
- Details of standard NHS treatment that this requested treatment will replace, if any.
- Expected benefits and risks of treatment.
- Any additional material considered to be relevant.
- The Clinical Team should refer to, and preferably include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient. Please note: it is the responsibility of the requesting clinician to supply evidence in support of this request, not the ICB/commissioner
- 2. This form should **NOT** be used to request funding for:
 - a. NICE Technical Appraisal Guidance approved interventions for specific indications if patients meets all criteria.
 - b. Treatment requiring prior authorisation.
 - c. Consideration of potential service developments where there is likely to be a group of patients with similar clinical circumstances who might also be candidates for this intervention.
 - d. Approved indications where funding is already sanctioned under an existing commissioning policy and where the patient meets the treatment criteria.
- 3. This form should **NOT** be used if there are likely to be other patients with similar clinical circumstances within the commissioning area who may also benefit from the treatment being requested. Where there are likely to be other similar patients **funding should be sought** through the submission of a business case. This is because the case represents a service development for a predictable population. You should discuss with your contract team how you submit a business case for consideration through the annual prioritisation round.
- 4. To minimise delays in the application process please ensure <u>ALL</u> fields are completed comprehensively and in a word processed format, font 11 and style Arial or similar. Incomplete forms or forms with insufficient levels of information will be returned to the requesting clinician and may result in a delay in the request being considered.

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- 5. Personal confidential data should be entered in sections 1 -5 **ONLY** repeated use of personal confidential data is not acceptable.
- 6. If reference is made to associated documentation, please indicate clearly which parts of this relate to each specific section
- 7. If you have received this pro-forma from the ICB please return a completed version within 6 weeks.
- 8. Cut off for submission to the non-urgent Panel is two weeks before the Panel sits. Please contact the IFR Department if you require the Panel date(s).
- 9. Clinicians should ensure that their organisation has agreed to submission of the request and the Trust Medical Director has countersigned the declaration below.

The directly relevant documents are:

- The Individual Funding Request Policy and process
- NICE IPG guidance where this exists.

DECLARATION

- 1. I confirm that it is not known or likely that there are any other patients within the responsible commissioner's population who are in the same (or similar) clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested intervention to the same or similar degree.
- I confirm that I have discussed this Individual Funding Request (IFR) with my patient. This request
 is being made with my patient's consent for the requested intervention and consent for the sharing
 of information regarding the IFR and payment relating to the requested intervention with the NHS
 Integrated Care Board and the public health department to enable the case to be fully researched and
 considered.
- 3. To the best of my knowledge I have given the most accurate and up to date information regarding this patient's clinical condition.

Signature of requesting clinician	Date				
Signature of Trust Medical Director	Date				
Organisation:					
Telephone: NHS.net Email:					
Correspondence Address:					

Please submit the completed form electronically to: cwicb.ardenifr@nhs.net OR by post to Coventry and Warwickshire Individual Funding Request (IFR) Team

NHS Coventry and Warwickshire Integrated Care Board, C/O Parkside House, Quinton Road, Coventry CV1 2NJ

PLEASE DO NOT HESITATE TO CONTACT THE IFR DEPARTMENT IF YOU WISH TO HAVE AN INITIAL DISCUSSION BEFORE MAKING A SUBMISSION OR BEFORE COMPLETING THE PROFORMA

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PLEASE READ THE GENERAL GUIDANCE ON PAGES 1 & 2 PRIOR TO COMPLETING THIS PROFORMA

For	Office Use Only				
Unic	ue Identifier:	Date received	:		
		•			=
		are completed in a word-pr	rocesse	d format and the declara	tion section on page 2 has
	signed and dated as re	equested			
	vention requested:				
(Nan	ne & type)				
('Inte	rvention' refers to the re	quested treatment, therapy o	r investig	native procedure – e.g. dru	ıg, surgical operation, medical
	ce, course of therapy.				
		ntion should be given in section	ons 16-1	8 below.)	
	osed provider				
	•	he proposed provider, postal number and nhs.net email add	trocc		
	nt Details:	difficer and fins.fiet email auc	11633		
ratie	in Details.				
1. P	atient name:	2. Date of birth:	3. Ag	je:	4. NHS No:
5. Ac	ldress:		6. GI	% Practice:	
7. He	eight	8. Weight	9. BI	ΛΙ	10. Smoker Yes/No
0	to at Dataila				
Con	tact Details:				
11.	Requesting Clinician				
	. •	name and contact details of	f clinicia	n	
		including postal address,			
	telephone number and	d nhs.net email address			
12.	Please provide name	of any other clinicians who yo	u have		
		vith and whether they agree	that the		
	request is appropriate				
13.		r us to contact the patient and Request Process and			confirm that you are taking full
	correspondence to		сору в	responsibility for infor	ming the patient.)
		en consent for the IFR team to ation from other clinicians in			
	their medical care		voived ii	ı	
Case	summary:				
14.	Diagnosis (i.e. Indica	ation for which the intervent	tion is re	equested)	
	Medical Condition:			· · · · · · · · · · · · · · · · · · ·	
	Relevant Past Medica	al History:			

15.	Please outline the case hi	story		
	The duration of the problem			
	Clinical severity (using standa	ard scoring if appropriate)		
	Other relevant diagnoses/co morbidities (including			
	mental health)			
	Prognosis			
16.	Summary of Previous Interventions for this condition	Dates	Nature of Intervention	Reason for stopping*/ response achieved
	Please outline any			
	treatment received to date			
	(non-pharmacological,			
	pharmacological, non-			
	surgical/surgical), the dates of each treatment and the			
	outcome in chronological			
	order.			
	*Reasons for stopping may			
	include:			
	☐ Course completed			
	No or poor responseDisease progression			
	Adverse effects/poorly			
	tolerated			
17.	What would be the 'standard'			
	pathway for a patient with this	s condition at this stage?		
18.	What other alternative interve	ntions (other than the		
	requested intervention) are	available?		

Deta	Details of exceptional circumstances:				
19.	a. An intervention that is covered by a relevant NICE Technology Appraisal or a local commissioning policy, but an exception to the policy.	(Pleas one bo		Please explain the exceptional circumstances in section 20 demonstrating: 1. The patient differs significantly from other patients who would not be offered this intervention under current policy; and 2. There is evidence to suggest that this patient will achieve greater benefit from the intervention than other patients with the same condition.	
	OR b. An intervention that is not currently routinely funded by the ICB, and for which no relevant national or local commissioning policy exist. (This covers any intervention not included within current local pathways and not agreed through NICE Technology Appraisals, the Local Delivery Plan, or specific local policy.)			Please explain in section 20 why you are seeking funding as an individual patient rather than a policy decision; and provide relevant evidence in section 32. If your justification for the request is that the clinical condition is rare, please give further incidence/prevalence information to support this.	
	OR c. A referral to a provider with which the ICB does not have a service level agreement for an intervention that could be provided within local pathways			Please explain the exceptional circumstances below in section 20.	
20.	Explanation of exceptional circumstances: Why is the standard intervention and existing care being requested in this case? Explain how the patie same treatment and would not funded in line with the	nt is sigr	nificantly	different to other patients who may wish to have the	
21.	Are you aware of any other similar patients who	would	Yes/ No	<u> </u>	
	benefit from this intervention? Would you expect to see other patients with the condition or presentation as this patient within the months?	same	. 23, . 10		

Deta	etails of intervention requested:				
22.	Please give details of the proposed intervention, inc	cluding (where relevant);			
	For devices/ prostheses please specify; what the device is and manufacturer				
	is and manarastars.				
	Would this be a discrete episode of care or ongoing care				
	Planned duration of intervention				
	When and how the patient will return to standard/local pathways of care				
23.	Estimated costs	<u>I</u>			
	Anticipated costs (inc VAT)	£ (Please indicate if cost is per year/cycle/course etc)			
	Are there any offset costs?				
	Describe the type & value of offset costs				
	Funding difference being applied for				
24.	Are there any additional associated costs?				
	(e.g. extra costs for delivery of intervention, additional				
	patient monitoring, maintenance and replacement costs for medical devices)				
25.	If this treatment is not approved, what other alternative treatment(s) will be offered to the patient?				
26.	How will you monitor the clinical effectiveness of this intervention?				
27.	Detail the current status of the patient prior to requested intervention.				
28.	What is the minimum time frame/course of treatment at which a clinical response can be assessed? (e.g. after a single course of treatment) Please outline any anticipated or likely adverse effects of the requested treatment for this patient.				
29.	What are the intended outcomes of this treatment? Please outline the expected outcomes (including the anticipated benefit over other available options) of the requested treatment in this patient				
30.	Is the requested intervention a continuation of existing treatment funded via another route?	No / Yes – give details of existing funding arrangement and why ceased			

s requested intervention part of a clinical trial?	Yes / No If Yes, give details (e.g. name of trial, is it an MRC / National trial?
s the drug funded through a clinical trial?	Yes/No
Full name of drug	
Name of manufacturer	
Planned dose and frequency	
Planned duration of intervention	
Route of administration	
Optimal start date	
Does the patient have allergies?	
If the intervention forms part of a regimen, please document in full	(e.g. Drug X as part of regimen Y (consisting of drug V, drug W, drug X and drug Z).
Drug licensed for requested indication in the UK?	Delete as appropriate: Yes / No (refer to pharmacy if required)
Has the Trust Drugs and	Delete as appropriate: Yes / No
Therapeutics Committee or equivalent Committee approved the requested intervention for use? (if drug or medical device)	If No , Committee Chair or Chief Pharmacist approved: Yes / No
Application reviewed by Chief Pharmacist or nominated deputy (in the case of a drug intervention)	Name: Email:
What is the anticipated toxicity of the intervention for this patient?	

Evid	ence	
32.	Please outline any relevant supporting evidence (including references). This should include any evidence supporting the likely clinical or cost effectiveness of this intervention in Supporting evidence should be as specific as possible to the intervention requested and the indications circumstances in this individual case.	,
33.	If you are citing clinical evidence in support of this request, please indicate the level of this as follows:	(Please tick one box)
	(i). Evidence from: meta-analysis of RCTs or at least two good quality RCTs	
	(ii). Evidence from one good quality RCT and supporting non-randomised (phase II) trials	
	(iii). Evidence from lower quality RCT(s) and/or more than one phase II study and/or good quality	
	observational studies	
	(iv). Evidence from single phase II study, case studies etc.	
	(v). Expert opinion	

Please note that cases will only be tabled to the Individual Funding Request Panel when we have received full information as requested above.

Failure to do so will result in a delay of your funding request

Appendix 2 - Request for funding form

ICB: Individual Case Patient No. Request for funding for xxxxxxxxxxxxx

. Background	
<u>. Evidence Summary</u>	
ntervention:	
ndications:	
ntended outcomes:	
Size of patient population:	
Ilternative treatments:	
vidence base:	
Costs:	

Appendix 3 - Individual Funding Request Panel

Terms of Reference

1. Introduction

1.1 The Individual Funding Request (IFR) Panel is established in accordance with NHS Coventry and Warwickshire Integrated Care Board's (the 'ICB') Constitution Standing Orders, Scheme of Reservation and Delegation, and Standing Financial Instructions.

2. Purpose

2.1 The IFR Panel makes decisions in respect of funding for individual cases. The IFR Panel will consider the evidence submitted in respect of a particular patient and reach a decision as to whether exceptional clinical circumstances have been demonstrated so as to justify a decision to allocate funding for this patient for the treatment sought, when the treatment is not routinely provided to the group of patients of which this patient is otherwise representative, or at all.

3. Authority

- 3.1 The IFR Panel is a formal sub-committee of the ICB's Board under the scheme of delegation and, as such, has delegated authority from the ICB's Board to make decisions in respect of funding for individual cases.
- For the avoidance of doubt, in the event of any conflict, the ICB's Standing Orders, Standing Financial Instructions and the Scheme of Reservation and Delegation will prevail over these terms of reference.

4. Reporting

4.1 The IFR Panel reports to the Quality, Safety and Experience Committee. An assurance report will be provided to the Quality, Safety and Experience Committee twice per annum and will highlight any individual decisions which may have implications for wider ICB commissioning policy.

5. Membership

- 5.1 The members of the IFR Panel are appointed by the Quality, Safety and Experience Committee.
- 5.2 A record will be made in the minutes of the Quality, Safety and Experience meeting when members are appointed to the IFR Panel and will include the names of the appointees
- 5.3 Membership of the IFR Panel will be as follows:
 - 1 x Chief Medical Officer or a deputy (Chair)
 - 1 x Executive Director or Director of the ICB
 - 2 x Clinicians practicing in the Coventry and Warwickshire footprint
 - 1 x Public Health Representative who holds an honorary contract with the ICB
 - 1x Mental Health/LDA/Joint Commissioning Lead as required for Mental Health/LDA/Joint Commissioning issues

The Chair of the IFR Panel will be the Chief Medical Officer/Deputy or their nominated alternate from among the other members of the IFR Panel.

Attendees at meetings

Review Date: December 2025

- 5.4 Other parties may be invited to attend the IFR Panel meeting to present cases.
- 5.5 IFR team members will attend to make a record of the proceedings and to provide general administrative support.
- 5.6 The IFR Team will be responsible for ensuring attendance of the delegated members. These members will also be available throughout the month to make decisions in respect of any urgent cases.
- 5.7 No individual who has currently, or has had, clinical involvement with a particular patient will be permitted to sit as an IFR Panel member for that case. The requesting clinician may attend to provide clarification of the evidence submitted. Clinicians attending for this purpose will be excluded from the subsequent IFR Panel discussion of the case.
- 5.8 Patients will not be invited to attend the IFR Panel hearing.

6. Meetings and Quorum

- 6.1 The Panel will meet as required but generally monthly.
- 6.2 Cases will be considered at the next available Panel meeting. If further information is required to prepare the case for consideration, this may delay presentation to the IFR Panel until the next or subsequent month.
- 6.3 In cases where urgent consideration is required, an extraordinary Panel meeting may be convened or another method of rapid discussion, e.g. via email, considered. Such decisions will be tabled at the next monthly IFR Panel and recorded in the minutes.
- 6.4 Cases will be anonymised before consideration by the Panel.
- 6.5 The IFR Panel will require the attendance of any 3 members to be quorate, one of which must be a clinician.
- 6.6 If there is not a unanimous decision in a particular case, the Chair of the IFR Panel will have the casting vote after taking account of all the clinical advice.
- 6.7 The IFR Panel may defer a case where additional information/clarification is required to enable a final decision to be made. The Chair will write to the clinician to detail what is required to allow further discussion of the case. If the additional information is not received within three months from the date of the Chair's letter to the Clinician, then the IFR Panel will reconsider the case and reach a decision based on the information available to it at that time.
- 6.8 The IFR Team, on behalf of the ICB, will produce letters for signature by the Chair, within five working days of the Panel meeting, to the patient (where this is not contra-indicated by the clinician on the initial pro-forma because direct communication is felt not to be in the patient's best interests) and to the referring clinician, setting out the IFR Panel's decision and the reasons for it.
- 6.9 Patients or clinicians who remain unhappy with an IFR Panel decision may request a review of the process by which the decision was reached.

7. Secretariat and administration

7.1 The IFR Panel will be provided with a secretariat function via the IFR Team of the ICB.

- 7.2 Papers will be distributed to members and other attendees at least 3 working days in advance of the meeting.
- 7.3 Formal minutes will be taken and shall include:
- 7.3.1 The names of all members and attendees present at the meeting;
- 7.3.2 Declarations of interest of members and attendees:
- 7.3.3 A record of matters discussed and agreed;
- 7.3.4 Matters arising and issues to be carried forward.

8. Conduct of the IFR Panel

- 8.1 Members of, and those attending, the IFR Panel shall behave in accordance with the ICB's Standing Orders and Standards of Business Conduct Policy.
- 8.2 The ICBs Conflicts of Interest Policy will apply and procedures to identify, declare and manage conflicts of interest must be followed at all times.

9. Review

- 9.1 These terms of reference and the effectiveness of the Panel will be reviewed at least annually and earlier if required.
- 9.2 All reviews will be logged in the Terms of Reference Review Log which is published in the Governance Handbook.
- 9.3 Any proposed amendments to the terms of reference will be submitted to the ICB's Board for approval.

Appendix 4 - Individual Funding Request Review Panel

Terms of Reference

1. Introduction

1.1 The Individual Funding Request (IFR) Review Panel is established in accordance with NHS Coventry and Warwickshire Integrated Care Board's (the 'ICB') Constitution Standing Orders, Scheme of Reservation and Delegation, and Standing Financial Instructions.

2. Purpose

- 2.1 Where an IFR Panel decision does not support funding for the treatment or therapy, a request to the IFR Review Panel can be made by the individual patient affected by the decision or by a carer, a parent/guardian or a clinician on behalf of that individual. Such a request may only be made on the ground that due process was not followed by the IFR Panel in reaching its original decision.
- 2.2 The IFR Review Panel's role is to decide whether the IFR Panel has properly followed its own procedures, has properly considered the evidence presented to it and has come to a reasonable decision based upon that evidence.

3. Authority

- 3.1 The IFR Review Panel is a Committee of the ICB's Board and part of the corporate governance process of the ICB.
- 3.2 The IFR Review Panel is the final arbiter of the decision in the IFR process.
- 3.3 For the avoidance of doubt, in the event of any conflict, the ICB's Standing Orders, Standing Financial Instructions and the Scheme of Reservation and Delegation will prevail over these terms of reference.

4. Reporting

- 4.1 The IFR Review Panel reports to the ICB's Board or Commissioning, Planning and Population Health Committee. Anonymised minutes of each meeting will be provided to the closed session of the ICB's Board on a bi-monthly basis. In addition, the IFR Team will provide a summary of decisions on an annual basis to the ICB's Board and will highlight any individual decisions which may have implications for wider ICB commissioning policy.
- 4.2 The Accountable Officer will be responsible for reporting the decision in confidential session to the ICB's Board.

5. Membership

- ICB Accountable Officer
- ICB Chair
- Another ICB Executive Officer (the Chief Delivery and Performance Officer being the usual first choice)

6. Meetings and Quorum

6.1 All three members must be present for the IFR Review Panel to be quorate. The Chair will be agreed by the panel members.

- 6.2 The IFR Review Panel cannot include a member of the IFR Panel which initially considered the case under appeal, although they can be in attendance to answer any questions the IFR Review Panel may have about how the request was handled by the IFR Panel. Patients and clinicians will not be invited to attend the IFR Review Panel meetings.
- 6.3 The IFR Review Panel will meet as and when required, when a request for review is lodged against a decision made by the IFR Panel.
- The IFR Team, on behalf of the IFR Review Panel will produce letters for signature by the Chair, to the patient/carer/parent/guardian and referring clinician giving details of the Panel's decision within five working days of the Review Panel meeting.

7. Secretariat and administration

- 7.1 The IFR Review Panel will be provided with a secretariat function via the IFR Team of the ICB.
- 7.2 Papers will be distributed to members and other attendees at least 3 working days in advance of the meeting.
- 7.3 Formal minutes will be taken and shall include:
 - 7.3.1 The names of all members and attendees present at the meeting;
 - 7.3.2 Declarations of interest of members and attendees;
 - 7.3.3 A record of matters discussed and agreed; and
 - 7.3.4 Matters arising and issues to be carried forward.

8. Conduct of the IFR Review Panel

- 8.1 Members of, and those attending, the IFR Review Panel shall behave in accordance with the ICB's Standing Orders and Standards of Business Conduct Policy.
- 8.2 The ICBs Conflicts of Interest Policy will apply and procedures to identify, declare and manage conflicts of interest must be followed at all times.

9. Review

- 9.1 These terms of reference and the effectiveness of the Review Panel will be reviewed at least annually and earlier if required.
- 9.2 All reviews will be logged in the Terms of Reference Review Log which is published in the Governance Handbook.
- 9.3 Any proposed amendments to the terms of reference will be submitted to the ICB's Board for approval.

Appendix 5 - Framework for identifying Individual Funding Requests that are exceptions

- 1) This policy recognises that there needs to be a distinction between cases where the patient's clinical circumstances are genuinely exceptional and those where the presenting clinical circumstances are representative of a group even a small group of other patients.
- 2) Where the presenting clinical circumstances are representative of a group of other patients, the policy of the ICB is that a decision to fund, or not to fund, is a policy decision and should not be taken in the form of a decision for an individual patient. This ensures that the outcome of the decision is applied equally to all the other patients who have the same presenting clinical circumstances, and that the principle of prioritisation is upheld.
- 3) The ICB and its constituent committees will at all times make decisions in accordance with the ICB's ethical framework, including the requirement to be mindful not to discriminate on grounds of gender, age, ethnicity, sexual orientation, educational attainment, employment, social or marital status, or religion, save where a difference in treatment is based on objectively justifiable factors and is a justified and proportionate response to the needs of different groups of patients.

4) Exceptionality

There can be no exhaustive definition of the facets of a condition which are likely to bring a particular case within the bracket of "exceptional". The word "exceptional" refers to something to which the general rule is not applicable.

5) Whilst everyone's individual circumstances are, by definition, unique, very few patients have clinical circumstances which are exceptional, so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance. However, the overriding question which an IFR Panel will need to ask itself is: has it been demonstrated that this patient's clinical circumstances are exceptional?

If a patient has a condition for which there is an established care pathway, the IFR Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that medical condition.

The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which an IFR Panel could find that a patient is exceptional.

6) However, the IFR Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was a genuinely exceptional circumstance. For example:

If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or is not clinically effective. if there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason), the fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that the patient is exceptional.

If the usual treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, the fact that the co-morbidity is present in this patient and its impact on treatment options for the requesting patient is unlikely to make the patient exceptional.

7) The most appropriate response in each of the above 2 situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a change to the policy adopted by the ICB for funding that patient pathway, so that a change can be made to that policy to benefit a subgroup of patients (of which this particular is potentially one such person). This change needs to be considered as a service development).

8) Non-clinical factors

It is common for an individual funding request to be put, at least in part, on the grounds that a patient's personal circumstances are exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed or is continuing to contribute to society. The ICB understands that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However, including non-clinical social factors in any decision-making raises at least three significant problems for the ICB:

- Across the population of patients who make such applications, the ICB is unable to make an
 objective assessment of material put before it relating to non-clinical factors. This makes it very
 difficult for the IFR Panel to be confident of dealing in a fair and even-handed manner in comparable
 cases.
- The essence of an individual funding application is that the ICB is making funding available on a one- off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the IFR decision making process, the ICB does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.
- The ICB is committed to a policy of non-discrimination in the provision of medical treatment. If for example, treatment was to be provided on the grounds that it would enable an individual to stay in paid work, then this would potentially discriminate in favour of those working, compared to those not working. To offer a treatment to one patient and not another on the basis that the funded patient was working and the patient denied funding was out of work would breach a principle on which the National Health Service was founded and still currently operates. The ICB has not been mandated to distribute resources based on these divisions within society. Such a decision would also set a precedent for the ICB always to favour those in work over those not currently in work. The same can be said of many other social factors such as having children / not having children, being a carer/not being a carer and so on. Granting requests to fund treatment for adolescents on the grounds that they wish to go to university (and therefore not funding treatment would inhibit the individual from fulfilling their true potential) or because of a person's role in society (e.g., professional) would also be discriminatory and would contribute to social inequality.
- 9) Generally, the NHS does not take into account social factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to normally provided care or treatment. It does not generally seek to deny treatment to those who may be thought to have caused or contributed to their own illnesses in some way, e.g., it does not deny treatment to those injured participating in sports in which they had voluntarily engaged.
- 10) In general, the NHS treats the presenting medical condition and does not inquire into the background factors which led to that condition as the basis on which to decide whether to make treatment available or not. The policy of the ICB is that it should continue to apply these principles in individual applications for funding approval. The ICB will therefore seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical social circumstances.

- 11) In reaching a decision as to whether a patient's circumstances are exceptional, the IFR Panel is required to follow the principles that non-clinical social factors, including social value judgments about the underlying medical condition or the patient's circumstances, are not relevant.
- 12) Clinicians will be asked to bear this in mind and not refer to social or non-clinical factors to seek to support the application for an IFR.

13) Proving the case that the patient 's circumstances are exceptional

The onus is on the requesting clinician to set out the grounds clearly for the IFR Panel on which it is said that this patient is exceptional. The grounds will usually arise out of an exceptional clinical manifestation of the patient's medical condition, as compared to the general population of patients with that medical condition.

- 14) These grounds must be set out on the pro-forma provided by the ICB and should clearly set out any factors which the clinician invites the IFR Panel to consider as constituting exceptional clinical circumstances. If, for example, it is said that the patient cannot tolerate the usual treatment because of the side effects of another treatment, the referring clinician must explain how usual it is for the patient with this condition not to be able to be provided with the usual treatment.
- 15) If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, then the IFR Panel is obliged to refuse the application. The IFR Panel recognises that the patient's referring clinician and the patient together are usually in the best position to provide information about the patient's clinical condition as compared to a subset of patients with that condition. The referring clinician is advised to set out the evidence in detail because the IFR Panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that specialty. The ICB therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.
- 16) There is no requirement for the IFR Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered neither to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, if a clear case of exceptionality is not made out on the paperwork placed before the IFR Panel, the Panel will be entitled to turn down the application.

17) Multiple claimed grounds of exceptionality

There may be cases where clinicians seek to rely on multiple grounds to show their case is exceptional. In such cases the IFR Panel should look at each factor individually to determine (a) whether the factor is, hypothetically, capable of making the case exceptional and (b) whether it does, in fact, make the patients case exceptional. The IFR Panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored. That is a judgment within the discretion of the IFR Panel.

18) If the IFR Panel is of the view that none of the individual factors on its own makes the patient's clinical circumstance exceptional, the IFR Panel should then look at the combined effect of those factors which are, in the IFR Panel's judgment, capable of supporting a possible finding of exceptionality. The IFR Panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional. In reaching that decision, the IFR Panel should remind itself of the difference between individual distinct circumstances and exceptional clinical circumstances.

19) The rule of rescue

The IFR Panel will not adopt the approach known as "the rule of rescue". The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at the same stage of progression are, to a greater or lesser extent, refractory to existing treatments, is unlikely to be sufficient, without more, to demonstrate exceptional circumstances.

20) IFR in the broader context of prioritisation

The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the ICB's resources. The IFR Panel is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments.

21) Individual Patient Requests for Funding for Treatments for Rare Conditions

The IFR Panel also has delegated authority from the ICB Board to consider requests for funding for interventions for rare conditions. Because there will not be a cohort of similar patients by comparison with whom the Individual Patient might be exceptional, as set out in the previous section of this policy, the IFR Panel will not, in Individual Patient cases, be considering whether or not the patient is exceptional. If incidence and prevalence criteria are both satisfied, as set out below, the IFR Panel will go on to consider the evidence for clinical and cost effectiveness and affordability.

- 22) For the purposes of this policy, an Individual Patient is defined by the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression.
- 23) Incidence is the number of new cases of a disease in a defined population within a specified period of time.
- 24) In order to satisfy the incidence criterion, the intervention for a particular condition at the same stage of progression as that of the Individual Patient is expected to be initiated for not more than three patients per million population per year (i.e. 3 patients across the ICBs' population per year).
- 25) Prevalence is the number of cases of a disease in a defined population at a particular point in time.
- 26) In order to satisfy the prevalence criterion, the total number of patients in receipt of the intervention for a particular condition at the same stage of progression as that of the Individual Patient should not be more than ten patients per million population at any one time (i.e. 10 patients across the ICBs' population).
- 27) A request for funding for an Individual Patient should be submitted in exactly the same way as for an IFR. The ICB expects the pro-forma submission to be supported by evidence of incidence and prevalence, as well as evidence of clinical effectiveness and cost effectiveness.
- 28) Cases will be prepared for and submitted to IFR Panel consideration as set out under the IFR policy. A Review process will likewise be available for patients who believe that the ICB did not follow its own procedures, failed to consider the evidence presented or came to an unreasonable decision upon that evidence.
- 29) Timescales will apply as set out for the respective stages of the IFR policy.

30) Experimental and Unproven Treatments

This section outlines how the IFR criteria will be interpreted and applied where the treatment being sought is, in itself, experimental or unproven.

- Where the case for clinical exceptionality has been accepted but the treatment is experimental or unproven, there is a particular need to scrutinise the likelihood that the treatment will be clinically effective and consider carefully whether funding the treatment would be a good use of NHS resources. This is because it is important that decisions on clinical practice and policy are based on sound clinical evidence. To ensure the effective and equitable use of NHS funding, experimental treatments have to be undertaken judiciously, responsibly and for clearly defined purposes.
- When an individual case has been found to be exceptional, the treatment proposed might, by definition, be considered to be unproven, and this is why the IFR Panel must carefully consider whether funding of such treatments is a good use of NHS resources as described above. However, this section of the policy applies to the particular categories of experimental or unproven treatment which are described below.

What is an experimental treatment?

A treatment may be considered experimental where any of these points apply:

- The treatment is still undergoing clinical trials and/or is a drug yet to undergo a phase III clinical trial for the indication in question;
- The treatment does not have marketing approval from the relevant government body for the indication in question;
- The treatment does not conform to a usual clinical practice in the relevant field;
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body; or
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

How are IFRs for experimental treatments considered?

- The experimental basis of the treatment will become relevant when the IFR Panel assesses the likely
 clinical effectiveness of the treatment for the patient and then, primarily, when the IFR Panel considers
 the degree of confidence it has on the safety and efficacy of the treatment for the patient and whether it
 would be a good use of NHS resources.
- Where evidence about the treatment is not yet available for public scrutiny, or there is limited evidence
 for one of the reasons set out above, the IFR Panel may have limited confidence in the evidence that has
 been presented.
- As preliminary requirements before agreeing to fund an experimental treatment, the ICB will need reassurance:
- That the decision to agree to an exception to the general policy on treatment for the condition is made for very clear and explicit reasons which are consistent with the ICB's priority setting principles; and
- That funding experimental treatments is done in a way that will contribute to the knowledge base.

- The IFR Panel will not fund treatment in response to an IFR if it considers that it would be
 more appropriate for the treatment to be the subject of research trials. Primary research into
 novel treatments should be progressed through the usual research funding routes and will
 not be funded through this IFR policy.
- The ICB will consider a funding request for an experimental treatment where there is either:
 - Evidence from small and often heterogeneous case reports;
 - Evidence solely of short term outcomes; or
 - Evidence of effectiveness in a similar condition to the clinical circumstance under consideration.
- In assessing whether to fund treatment in these cases, the ICB will make a decision having regard to:
 - The potential benefit and risks of the treatment; and
 - The biological plausibility of benefit based on other evidence; and
 - An estimate of cost of the treatment and the anticipated value for money; and
 - The priority of the patient's needs compared to other competing needs and unfunded developments.
- The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based and costs, as well as clinically relevant information on the patient and factors that indicate a good response to treatment. In addition, the clinician must identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.
- The options for consideration by the ICB in these instances are:
 - Not to fund;
 - Fund a trial of treatment but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team. This option is only available where there is a course of treatment or long-term treatment. It is not suitable for on one-off treatment such as a surgical intervention;
 - In all cases, contribution to any relevant clinical database or population registry which is operating.

31) Funding for cases following a Clinical Trial

Save in the most exceptional cases, the ICB does not anticipate that it will agree a request under this IFR policy to fund patients at the end of a clinical trial. This is because arrangements to continue treatments from which patients have benefited during a trial should be agreed with the sponsor of the research at the outset of the trial and information should have been given to patients as part of the process of patients signing up to participate in the trial. Even if this is not the case, patients coming out of a clinical trial will almost inevitably represent a group of patients for whom a policy should be developed under the Service Development planning because there will be a number of patients in broadly the same clinical circumstances, and so it is very unlikely that the patient will be able to show clinical exceptionality within this policy.

Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.

Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

Quality Impact Assessment

Quality and Equality Impact Assessment

Scheme Title:	Individual Funding Request Policy			
Project Lead:	Lucy Dyde, IFR Team Manager Senior Responsible Officer: Dr Angela Brady			
		Quality Sign Off:	Anita Wilson	
Intended impact of scheme:	To provide a process where a patient is suffering from a medical condition for which the ICB has commissioning responsibility and either the ICB has no commissioning policy in respect of the treatment for which funding is sought, the patient does not fulfil the criteria for eligibility for treatment set out in the policy or the ICB has a policy stating that it will not routinely fund the drug or intervention for any patient.			
How will it be achieved:	Through the process detailed in this document.			

Name of person completing assessment:	Lucy Dyde
Position:	IFR Team Manager
Date of Assessment:	15 March 2023

Quality Review by:	Mary Mansfield
Position:	Deputy Director of Nursing
Date of Review:	15 March 2023

High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)		Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions	
		Positive	Negative	Neutral		Risk impact	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme	Effectiveness – clinical outcome			√					
negatively on any	Patient experience			√					
	Patient safety			√					
	Parity of esteem			√					
	Safeguarding children or adults			√					
NHS Outcomes Framework	Enhancing quality of life			√					

Could the scheme impact positively or negatively on the delivery of the five	Ensuring people have a positive experience of care	√			
domains:	Preventing people from dying prematurely	√			
	Helping people recover from episodes of ill health or following injury	√			
	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓			
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple longterm conditions and clinical risk factors	I			
	Access to the highest quality urgent and emergency care	√			
	Convenient access for everyone	✓			
	Ensuring that citizens are fully included in all aspects of service design and change	✓			
	Patient Choice	✓			

	1		1	1		
	Patients are fully empowered in their own care	√				
	Wider primary care, provided at scale	✓				
Access Could the proposal	Patient choice	✓				
impact positively or negatively on any	Access	✓				
of the following:	Integration	✓				
Compliance with NHS Constitution	Quality of care and environment	✓				
	Nationally approved treatment/drugs	✓				
	Respect, consent and confidentiality	✓				
	Informed choice and involvement	✓				
	Complain and redress	✓				

^{*}Risk score definitions are provided in the next section.

Equality Impact Assessment

What is the aim of the project / policy?

Project / Policy Details

To provide a process where a patient is suffering from a medical condition for which the ICB has
commissioning recognition and either the ICR has no commissioning policy in respect of the treatment

commissioning responsibility and either the ICB has no commissioning policy in respect of the treatment for which funding is sought, the patient does not fulfil the criteria for eligibility for treatment set out in the policy or the ICB has a policy stating that it will not routinely fund the drug or intervention for any patient.

Who will b etc.	e affected by thi	s work? e.g staf	f, patients, serv	ice users, partner	organisations
Patients					

Is a full Equality Analysis Required for this project?				
Yes	Proceed to complete this form.	No	Explain why further equality analysis is not required.	

If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.

1. Evidence used

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

NHS England Standard operating procedures: Individual funding requests policy

2. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Disability: A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Gender reassignment (including transgender): Where a person has proposed, started or completed a process to change his or her sex.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Marriage and civil partnership: A person who is married or in a civil partnership.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Pregnancy and maternity: A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry

and Warwickshire Integrated Care Board from applying this policy.

Race: A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Religion or belief: A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Sex: A man or a woman

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Sexual orientation: Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Carers: A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Other disadvantaged groups:

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

3. Human Rights		
FREDA Principles / Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	To provide an fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board where

		a patient is suffering from a medical condition for which the ICB has commissioning responsibility and either the ICB has no commissioning policy in respect of the treatment for which funding is sought, the patient does not fulfil the criteria for eligibility for treatment set out in the policy or the ICB has a policy stating that it will not routinely fund the drug or intervention for any patient. Patients will be kept informed of the progress of the IFR as it moves through the different Tiers, as detailed within the policy (unless advised otherwise by the requesting clinician). Patients will have the opportunity to provide written/audio evidence, as detailed within the policy.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	The requesting clinician will confirm whether the patient consents to the application and whether the patient is to be contacted, as per the proforma.
		All patient identifiable information will be redacted, as detailed within the policy. All written communication to the patient will be marked Private and Confidential.
		All communication, written or verbal, will be provided in a clear, understandable, format.
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have	This policy is applied to all patients of the NHS Coventry and Warwickshire Integrated

	their needs met and identified?	Care Board where the clinician has identified a need for an IFR. Patients will have the opportunity to provide written/audio evidence, as detailed within the policy.
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Patients will be kept informed of the progress of the IFR as it moves through the different Tiers, as detailed within the policy (unless advised otherwise by the requesting clinician). All written communication to the patient will be marked Private and Confidential. All communication, written or verbal, will be provided in a clear, understandable, format
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Patients have the opportunity submit their own evidence for consideration by the IFR panel by written or audio submission. All written communication to the patient will be marked Private and Confidential. All communication, written or verbal, will be provided in a clear, understandable, format
Right to Life	Will or could it affect someone's right to life? How?	No
Right to Liberty	Will or could someone be deprived of their liberty? How?	No

4. Engagement, Involvement and Consultation						
If relevant, please state what engagement activity has been undertaken and the date and with						
which protected groups:	which protected groups:					
Engagement Activity Protected Characteristic/ Date						
Group/ Community						

N/A	N/A	N/A
For each angagement activity, pl	ease state the key feedback and h	now this will shape policy /
service decisions (E.g. patient to	ld us So we will):	low this will shape policy /
N/A		

5. Mitigations and Changes

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

N/A	

6. How will you measure how the proposal impacts health inequalities?

e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities.

You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.

This is an amendment to an existing ICB policy and the process remains unchanged. The following amendments have been made:

- Formatting changes
- Amendment: reference to Arden Commissioning Support Unit removed
- Update to IFR panel membership; GPs replaced with Clinicians
- Pronouns removed.

IFR decisions are reported on a bi-monthly and annual basis to the Commissioning, Planning & Population Health Committee.

7. Is further work required to complete this assessment?

Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).

Work needed	Section	When	Dare completed
N/A	N/A	N/A	N/A

8. Sign off

The Equality Analysis will need to go through a process of **quality assurance** by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.

Requirement	Name	Date
Senior Manager Signoff	Michael Caley, Deputy CMO	24/3/23
Which committee will be considering the findings and signing off the EA?	Quality, Safety and Experience Committee	27/06/23
Approved by the Policy Procedure and Strategy Assurance Group.		

Once complete, please send to the ICB's Governance Team