NHS
Surrey Downs
Clinical Commissioning Group

Operating Process for dealing with Procedures of Limited Clinical Effectiveness (PoLCE) and Assisted Conception

Policy number:	CL14
Version:	1
Ratified by:	Executive Management Team
Name of originator/author:	Andrea Golding
Name of responsible committee/individual:	Andrea Golding
NHSLA Standard (if applicable):	
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Improving care together across Surrey Downs

Version History

Version Number	Date	Name of Reviewer	Ratification Process	Notes
0.1 (1st draft)	May 2016	Andrea Golding	For approval by Surrey Priorities Committee	
1 (1st approved version)	August 2016	Andrea Golding/ Steph Bennett	For final sign off by SD CCG Executive Management Team	

Equality statement

Surrey Downs Clinical Commissioning Group ("Surrey Downs CCG") aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the Human Rights Act 1998 and promotes equal opportunities for all. This document has been assessed to ensure that no-one receives less favourable treatment on grounds of their gender, sexual orientation, marital status, race, religion, age, ethnic origin, nationality, or disability. Members of staff, volunteers or members of the public may request assistance with this policy if they have particular needs. If the person requesting has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.
Surrey Downs CCG embraces the six staff pledges in the NHS Constitution. This policy is consistent with these pledges.

Equality analysis

This policy has been subject to an Equality Analysis, the outcome of which is recorded below.

		Yes, No or N/A	Comments
1.	Does the document/guidance affect one group less or more favourably than another on the basis of:		
	Age Where this is referred to, it refers to a person belonging to a particular age (e.g. 32 year olds) or range of ages (e.g. 18 - 30 year olds).	No	

	Disability A person has a disability if s/he has a physical 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.	No	
	Gender reassignment The process of transitioning from one gender to another.	No	
	Marriage and civil partnership In England and Wales marriage is no longer restricted to a union between a man and a woman but now includes a marriage between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'. Civil partners must not be treated less favourably than married couples (except where permitted by the Equality Act).	No	
	Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.	No	
	Race Refers to the protected characteristic of Race. It refers to a group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins	No	
	Religion and belief Religion has the meaning usually given to it but belief includes religious and philosophical beliefs including lack of belief (e.g. Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition	No	
	Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes	No	

2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the document/guidance likely to be negative?	No	
5.	If so, can the impact be avoided?	N/A	
6.	What alternative is there to achieving the document/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

For advice in respect of answering the above questions, please contact the Corporate Office, Surrey Downs CCG. If you have identified a potential discriminatory impact of this procedural document, please contact as above.

Names and Organisation of Individuals who carried out the Assessment	Date of the Assessment
Clare Johns (Lead Commissioning Technician , Surrey Downs CCG	June 2016
Jonathan Perrott (Business Manager, Surrey Downs CCG)	

Contents

Operating Process for dealing with Procedures of

Limited Clinical Effectiveness and Assisted Conception

1. Introduction

This document sets out the procedures for dealing with treatments not routinely commissioned or procedures which are restricted to clinical criteria. These are referred to as Procedures of Limited Clinical Effectiveness ("PoLCE"). This Operating Policy should be read in conjunction with the Procedures of Limited Clinical Effectiveness (PoLCE) policy which provides a list of all procedures that are considered to be PoLCEs and the Assisted Conception policy.

1.1 What is a Procedure of Limited Clinical Effectiveness (PoLCE)?

A PoLCE is a procedure for which the clinical effectiveness of that procedure is either absent or evidence shows weak efficacy and few long term benefits. It could be a procedure which is clinically effective but only under certain conditions or when a person meets certain criteria. If those conditions or criteria are not met, then alternative forms of treatment (often more conservative) should be tried first. If a PoLCE is not funded because the conditions or criteria are not met, research has already shown that this will not result in a significantly adverse effect on the patient's physical health.

1.2 GP Discussion

When a patient visits their GP to discuss a procedure that is listed within the PoLCE policy, the GP will consider whether the patient fully meets the criteria relating to that particular procedure.

If, in the GP's clinical opinion, the patient fully meets the criteria then they should refer the patient for an assessment with an appropriate NHS treatment provider through e-Referrals (Choose and Book). However, if the patient does not fully meet the relevant criteria, the GP should advise the patient that the CCG will not fund the requested procedure and treat the patient's condition with appropriate alternatives.

If a patient does not meet the criteria, but the GP strongly believes their clinical presentation is either rare* or exceptional**, the GP may feel it is appropriate to refer the patient to a consultant for a further opinion to assess whether or not they may be eligible for an Individual Funding Request ("IFR") . If they are eligible, an IFR application would need to be made by the consultant or clinician that will be providing the treatment. This is subject to the terms of SD CCG's IFR Policy.

*The definition of rarity is 1:2.5 million
**The definition of exceptionality is the CCG will consider whether the patient's clinical circumstances are outside of the range of clinical circumstances presented by at least

95% of patients with the same medical condition at the same stage of progression. The patient's clinical circumstances must be shown to be sufficiently unusual that they could properly be described as being exceptional.

GP's should make patients aware that a referral for an assessment with a consultant does not guarantee funding approval.

2. PoLCE Process

(See Appendix 1 for PoLCE process map)

2.1 Application Process

2.1.1 Prior Approval form

A Prior Approval form is required for ALL procedures listed within the PoLCE policy. Any treatment that takes place without a Prior Approval form will not be paid for.

2.1.2 Who can submit a Prior Approval Form?

Prior Approval forms must only be submitted to the CCG by an NHS consultant, GP or an equivalent autonomous practitioner provided s/he will be responsible for administering the treatment ("the requesting clinician").

Prior Approval forms should only be submitted when the patient fully meets the criteria for the procedure requested.

If a patient does not fully meet the criteria for a procedure listed within the PoLCE policy and the requesting clinician is able to demonstrate that the patient is either rare or clinically exceptional (as described above), an online IFR application form must be submitted using the secure online Blueteq database. The CCG will consider the IFR application in accordance with the terms of its IFR Policy.

It is the responsibility of the requesting clinician completing the Prior Approval form to confirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the Prior Approval form is submitted.

2.1.3 Accessing Blueteq in order to submit a Prior Approval form

In order for a clinician to submit a Prior Approval form using the secure online Blueteq database, they will need to be registered as a user.

A user name and password are required to log on; clinicians can obtain this by emailing tnrf@blueteq.co.uk and providing them with a full name, job title, nhs.net or nhs.uk email address, and their employer name. They must specify that they wish to register for the IFR portal.

Once registered, clinicians should visit https://blueteq-secure.co.uk/trust. Please note; Blueteq works best through Internet Explorer.

Please note: if are registered for both Individual Funding Requests (IFR) and Hi-Cost Drugs, the clinician will need to select which "trust mode" they will be working on. This does not apply if the clinician is only registered for IFR's.

2.1.4 Submitting a Prior Approval form

All Prior Approval forms completed will be populated by the secure Blueteq database and a unique identifier will be created.

A process map for Prior Approval's is included within this policy (Appendix 1).

Once received, a response will be provided to the requesting clinician within 72 hours. The CCG may approve the proposed PoLCE procedure or refuse it, depending on whether the relevant criteria and/or conditions are met.

If additional information is required to support the request, the IFR Team will contact the clinician via the Blueteq database. The clinician will have 5 working days in which to respond to the IFR Team. If no response is received then a reminder message will be sent advising that if the requested information is not received within 3 working days the request will be withdrawn and the procedure will not be authorised to take place.

2.1.5 Auditing

All procedures which take place following the submission of a Prior Approval form will be subject to a periodic audit by the CCG.

3. Assisted Conception process

(See Appendix 2 for Assisted Conception process map)

3.1 Application process

3.1.1 Prior Approval form

A Prior Approval form is required for ALL procedures listed within the Assisted Conception Policy unless the case has funding approval following a formal IFR application.

All Prior Approval forms must be completed online using the secure online Blueteq database and should only be submitted by the clinician administering the treatment.

The onus is on the requesting clinician to ensure that a Prior Approval form is submitted prior to treatment taking place. Any treatment that takes place without a Prior Approval form will not be paid for.

3.1.2 Who can submit a Prior Approval form?

Prior Approval forms for IVF must only be submitted **by the IVF Clinic that will be** responsible for administering the treatment ("the requesting clinician").

Prior Approval forms should only be submitted when the patient fully meets the criteria for the procedure requested.

It is the responsibility of the requesting clinician completing the Prior Approval form to confirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the Prior Approval form is submitted.

If the male patient requires either Sperm Retrieval or Sperm Freezing, then the IVF Clinic must submit a separate online Prior Approval form for this treatment.

3.1.3 Accessing Blueteq in order to submit a Prior Approval form

In order for a clinician to submit a Prior Approval form using the secure online Blueteq database, they will need to be registered as a user.

A user name and password are required to log on; clinicians can obtain this by emailing tnrf@blueteq.co.uk and providing them with a full name, job title, nhs.net or nhs.uk email address, and their employer name. They must specify that they wish to register for the IFR portal.

Once registered, clinicians should visit https://blueteq-secure.co.uk/trust. Please note; Blueteq works best through Internet Explorer.
Please note: if are registered for both Individual Funding Requests (IFR) and Hi-Cost Drugs, the clinician will need to select which "trust mode" they will be working on. This does not apply if the clinician is only registered for IFR's.

3.1.4 Submitting a Prior Approval form

As described above under paragraph 2.1.4 all Prior Approval forms completed will be populated by the secure Blueteq database and a unique identifier will be created.

A process map for Prior Approval's for assisted conception is included within this policy (Appendix 2).

Once received, a response will be provided to the requesting clinician within 72 hours. If additional information is required to support the request, the IFR Team will contact the clinician via the Blueteq database. The clinician will have 5 working days in which to respond to the IFR Team. If no response is received then a reminder message will be sent advising that if the requested information is not received within 3 working days the request will be withdrawn and the procedure will not be authorised to take place.

3.1.5 Auditing

All procedures which take place following the submission of a Prior Approval form will be subject to a periodic audit by the CCG.

4. Policy Approval, Ratification and Review Process

This policy will be subject to review after one year and at any stage at the request of management or following a change in legislation or national guidance.

5. Policy dissemination and Implementation

Dissemination of this document will be organised centrally and disseminated and implemented as follows:

- A copy of the policy will be held on the CCG website
- A copy of the policy will be sent to all GPs and Providers within the CCG
- Managers will convey the contents of the policy to members of staff and ensure they have read and understood the document and abide by its contents
- The policy will be shared with all relevant stakeholders.
- This policy will be brought to the attention of all staff and monitored in line with normal assurance processes.

6. Glossary

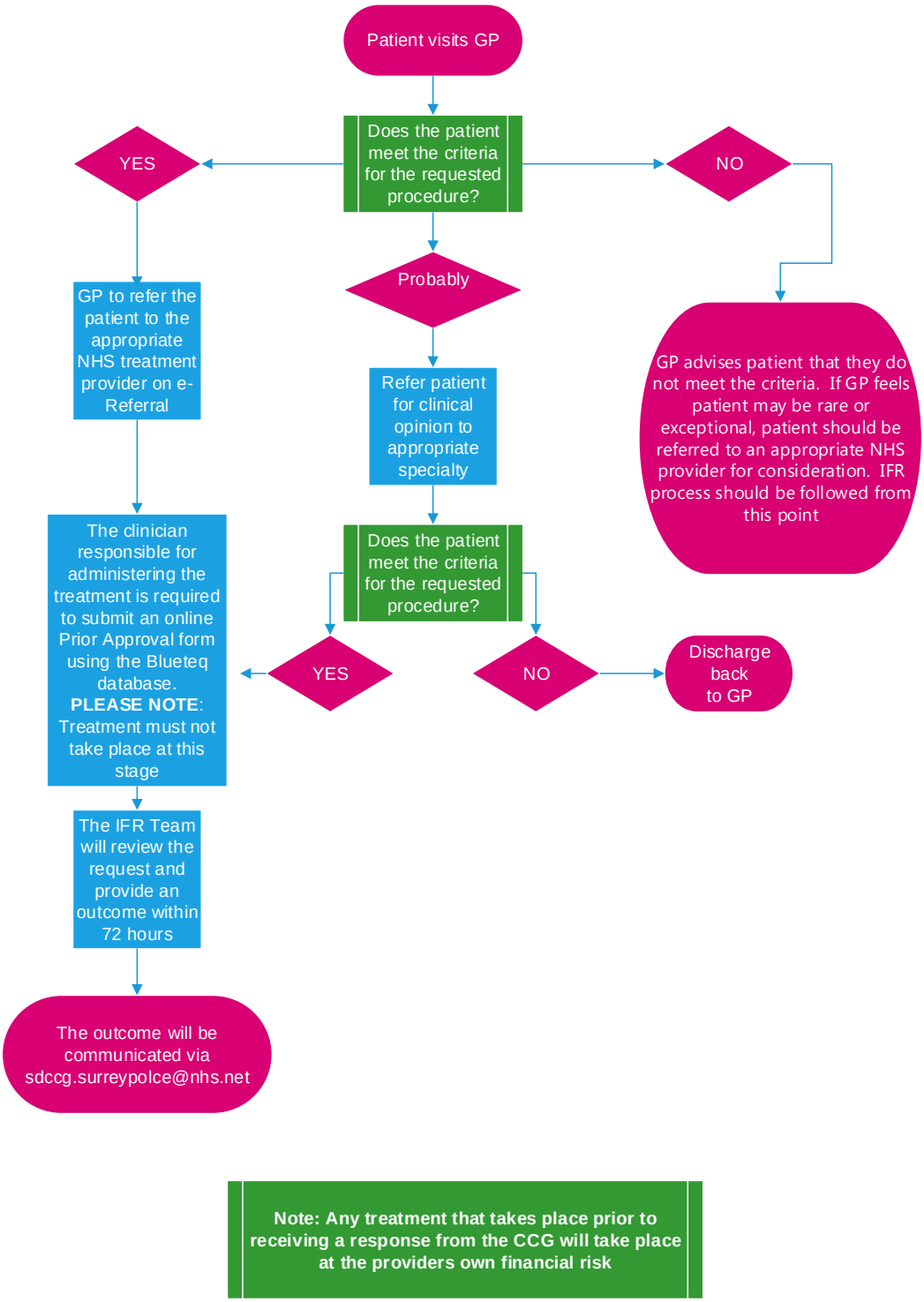
- CCG: Clinical Commissioning Group
- IFR(s): Individual Funding Request(s)

7. Appendices

- Procedures of Limited Clinical Effectiveness (PoLCE) : Prior Approvals process map (TNRF2)

- Assisted Conception process map

Procedures of Limited Clinical Effectiveness (PoLCE): Prior Approvals Process Map (Policy No. TNRF2)



Note: Any treatment that takes place prior to receiving a response from the CCG will take place at the providers own financial risk

Note: Any treatment that takes place prior to receiving a response from the CCG will take place at the providers own financial risk

Assisted Conception Process Map