NHS
Southend
Clinical Commissioning Group

Specialist Fertility Services Commissioning Policy

Author:	EoE CCG Fertility Consortium
Version No:	5
Policy Effective from:	1st February 2018

This policy replaces all previous versions. Where patients have commenced treatment in any cycle prior to this version becoming effective, they are subject to the eligibility criteria and scope of treatment set out in the relevant version.

Previous versions of this policy:

Version 1 – Effective 15 August 2008 to 30 June 2010

Version 2 – Effective 1 July 2010 to 31 May 2011

Version 3 – Effective 1 June 2011 to 30 November 2014

Version 4 – Effective 1 December 2014 to 31 January 2018

Version 5 – Effective following agreement by the Governing Body (1st February 2018)

Document Reader Information

Policy HR/Workforce Management Planning Clinical	Estates Performance IM&T Finance Partnership Working
Document Purpose	Policy
Reference Number	
Title	Fertility Services Commissioning Policy
Author	EoE CCG Fertility Consortium
Publication Date	1st February 2018
Target Audience	CCGs, NHS Trusts, Tertiary Providers, commissioners, directors of finance, GPs, fertility nurses, service users
Circulation List	All of the above
Description	The EOE Consortium Commissioning Policy for Fertility Services
Cross Reference	EOE Consortium Fertility Services Specification NICE Guideline CG156
Superseded Docs	Individual PCTs documentation in the EOE commissioning fertility services
Action required	For dissemination within primary, secondary and tertiary care providers
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Fertility treatment and referral criteria for tertiary level assisted conception

1. Introduction

1.1.1 This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services for the population of Southend CCG, along with the commissioning responsibilities and service provision.

1.1.2 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.

1.1.3 The paper specifically sets out the entitlement and service that will be provided by the NHS for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI). These services are commissioned by Clinical Commissioning Groups and provided via tertiary care providers.

1.1.4 It is the purpose of the criteria set out in this policy to make the provision of fertility treatment fair, clear and explicit. This paper should be read in conjunction with NICE Guidance CG156 "Fertility: assessment and treatment for people with fertility problems" (2013, updated September 2017) available on their website at http://www.nice.org.uk/guidance/cg156

1.2 Review

This policy will be reviewed regularly and within 3 months of any legislative changes that should or may occur in the future. The date of the next review will be February 2019.

2. Commissioning responsibility

2.1.1 Specialist fertility services are considered as Level 3 services or tertiary services. Preliminary Levels 1 & 2 are provided and commissioned within primary care and secondary services such as acute trusts. To access Level 3 services the preliminary investigations should be completed at Level 1 & 2.

2.1.2 Specialist Fertility Treatments within the scope of this policy are:

- In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI)
- Surgical sperm retrieval methods
- Donor Insemination (DI)
- Intra Uterine Insemination (IUI) unstimulated
- Sperm, embryo and male gonadal tissue cryostorage and replacement techniques
- Egg donation where no other treatment is available
- Blood borne viruses (ICSI + sperm washing)
- Egg and sperm storage for patients undergoing cancer treatment

2.1.3 Treatments excluded from this policy:

- Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England
- Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England
- Surrogacy

2.1.4 Formal IVF commissioning arrangements support this policy including a contract between ENHCCG (with delegated responsibility for procurement) and each tertiary centre. Quality Standards and clinical governance arrangements are in place with these centres. Outcomes are monitored and performance managed in accordance with the Human Fertilisation & Embryology Authority Licensing requirements or any successor organisations.

2.1.5 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.

2.1.6 Couples who do not meet the criteria and consider they have exceptional circumstances should be considered under the Individual Funding Request (IFR) policy of their CCG. All IFR funding queries should be directed to the IFR team of the relevant CCG who may liaise with the central contracting team. Funding of such exceptional cases is the responsibility of the CCG.

2.1.7 Couples will be offered a choice of providers that have been commissioned by the CCG.

3. Specialist Fertility services policy and criteria

3.1.1 The CCG only commissions the following fertility techniques regulated by the Human Fertilisation & Embryology Authority (HFEA).

3.2 In-Vitro Fertilisation (IVF)

3.2.1 An IVF procedure includes the stimulation of the women's ovaries to produce eggs which are then placed in a special environment to be fertilised. The fertilised eggs are then transferred to the woman's uterus.

3.2.2 For women less than 40 years (eligible for treatment up to 39 years and 364 days providing funding approvals obtained in advance of treatment) this policy supports a maximum of 2 embryo transfers with one cycle of IVF, with or without ICSI, this includes any abandoned cycles. Any previous full IVF cycles, whether self- or NHS-funded, will count towards the total number of full cycles offered by the relevant CCG. To clarify, women up to the age of 40 years and meeting all eligibility criteria will be able to access one cycle of IVF funded by the CCG.

3.2.3 A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). This will include the storage of any frozen embryos for 1 year following egg collection. Patients should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage will need to be funded by themselves or allowed to perish.

3.2.5 An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

3.2.6 Before a new fresh cycle of IVF can be initiated any previously frozen embryo(s) must be utilized.

3.2.7 Where couples have previously self-funded a cycle then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

3.2.8 Embryo transfer strategies:

- only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.

3.2.9 A fresh cycle would be considered completed with the attempt to collect eggs and transfer of a fresh embryo.

3.2.11 If a cycle is commenced and ovarian response is poor, a clinical decision would need to be taken as to whether a further cycle should be attempted, or if the use of a donor egg may be considered for further IVF cycles.

3.2.12 If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.

3.2.13 Clinical Indications:

3.2.13.1 In order to be eligible for treatment, Service users should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of 3 years. There is no criterion for couples with a diagnosed cause of infertility – see below:

(a) Tubal damage, which includes:
- Bilateral salpingectomy
- Moderate or severe distortion not amenable to tubal surgery

(b) Premature Menopause (defined as amenorrhoea for a period more than 6 months together with a raised FSH (follicle stimulating hormones) >25 and occurring before age 40 years)

(c) Male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values*:
- semen volume: 1.5 ml or more
- pH: 7.2 or more
- sperm concentration: 15 million spermatozoa per ml or more
- total sperm number: 39 million spermatozoa per ejaculate or more
- total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility
- vitality: 58% or more live spermatozoa
- sperm morphology (percentage of normal forms): 4% or more.

(d) Ovulation problems adequately treated but not successfully treated i.e no successful pregnancy achieved

(e) Endometriosis where Specialist opinion is that IVF is the correct treatment

(f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply)

3.3 Surgical Sperm Recovery

3.3.1 Surgical sperm retrieval methods included for service provision aretesticular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA).

3.3.2 Micro surgical Sperm recovery is not routinely funded and must be considered as an IFR application to the relevant CCG.

3.3.3 Sperm recovery techniques outlined in this section are not available to patients who have undergone a vasectomy.

3.4 Donor insemination

3.4.1 The use of donor insemination is considered effective in managing fertility problems associated with the following conditions:
- obstructive azoospermia
- non-obstructive azoospermia
- severe deficits in semen quality in couples who do not wish to undergo ICSI.

- Infectious disease of the male partner (such as HIV)
- Severe rhesus isoimmunisation
- Where there is a high risk of transmitting a genetic disorder to the offspring

3.4.2 Donor insemination is funded up to a maximum of 6 cycles of Intrauterine Insemination (IUI).

3.5 Donor semen as part of IVF/ICSI

3.5.1 Donor semen is used for same sex couples as part of IVF/ICSI treatment.

3.5.2 Funded up to same number of cycles of IVF.

3.6 Intra Uterine Insemination (IUI)

3.6.1 NICE guidelines state that unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse:

- people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm
- people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
- people in same-sex relationships

3.6.2 Due to poor clinical evidence, a maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will only be offered under exceptional circumstances and an IFR application for funding must be made to the CCG.

3.7 Egg donation where no other treatment is available

3.7.1 The patient may be able to provide an egg donor; alternatively, the patient can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

3.7.2 This will be available to women who have undergone premature ovarian failure (amenorrhoea >6 months and a raised FSH >25) due to an identifiable pathological or iatrogenic cause before the age of 40 years or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

3.8 Egg and Sperm storage for patients undergoing cancer treatments

3.8.1 When considering and using cryopreservation for people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow recommendations in 'The effects of cancer treatment on reproductive functions' (2007).

3.8.2 When using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocyctes.

3.8.3 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile.

3.8.4 Local protocols should exist to ensure that health professionals are aware of the values of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively.

3.8.5 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if:

- they are well enough to undergo ovarian stimulation and egg collection and
- this will not worsen their condition and
- enough time is available before the start of their cancer treatment.

3.8.6 Cryopreserved material may be stored for an initial period of 10 years.

3.8.7 Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria.

3.9 Pre-implantation Genetic Diagnosis (PGD)

3.9.1 This policy does not include pre-implantation genetic screening as it is not considered to be within the scope of fertility treatment. This service is commissioned by NHS England. Providers should seek approval from Specialist Commissioning NHS England.

3.10 Chronic Viral Infections

3.10.1 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. requires the use of ICSI technology.

3.10.2 As per NICE guidance (section 1.3.9). Do not offer sperm washing not offered as part of fertility treatment for men with hepatitis B.

3.10.3 This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and therefore potentially her unborn baby.

3.11 Privately funded care

3.11.1 This policy covers NHS funded fertility treatment only. For clarity, Patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the Secondary or Tertiary Provider or experimental treatments.

3.11.2 Where a patient meets this eligibility criteria but agrees to commence treatment on a privately funded basis, they may not retrospectively apply for any associated payment relating to the private treatment.

3.12 Surrogacy

3.12.1 Surrogacy is not commissioned as part of this policy. This includes part funding during a surrogacy cycle.

4 Referrals

4.1 Couples who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The patients will be assessed within the Primary and Secondary Care setting.

4.2 A decision to refer a couple for IVF or other fertility services will be based on an assessment against this eligibility Criteria which is based on the NICE guidelines and the HFEA recommendations as detailed in the clinical pathways.

4.3 Referral to the tertiary centre will be via a consultant gynaecologist or GP with Special Interest (GPSI) in primary care.

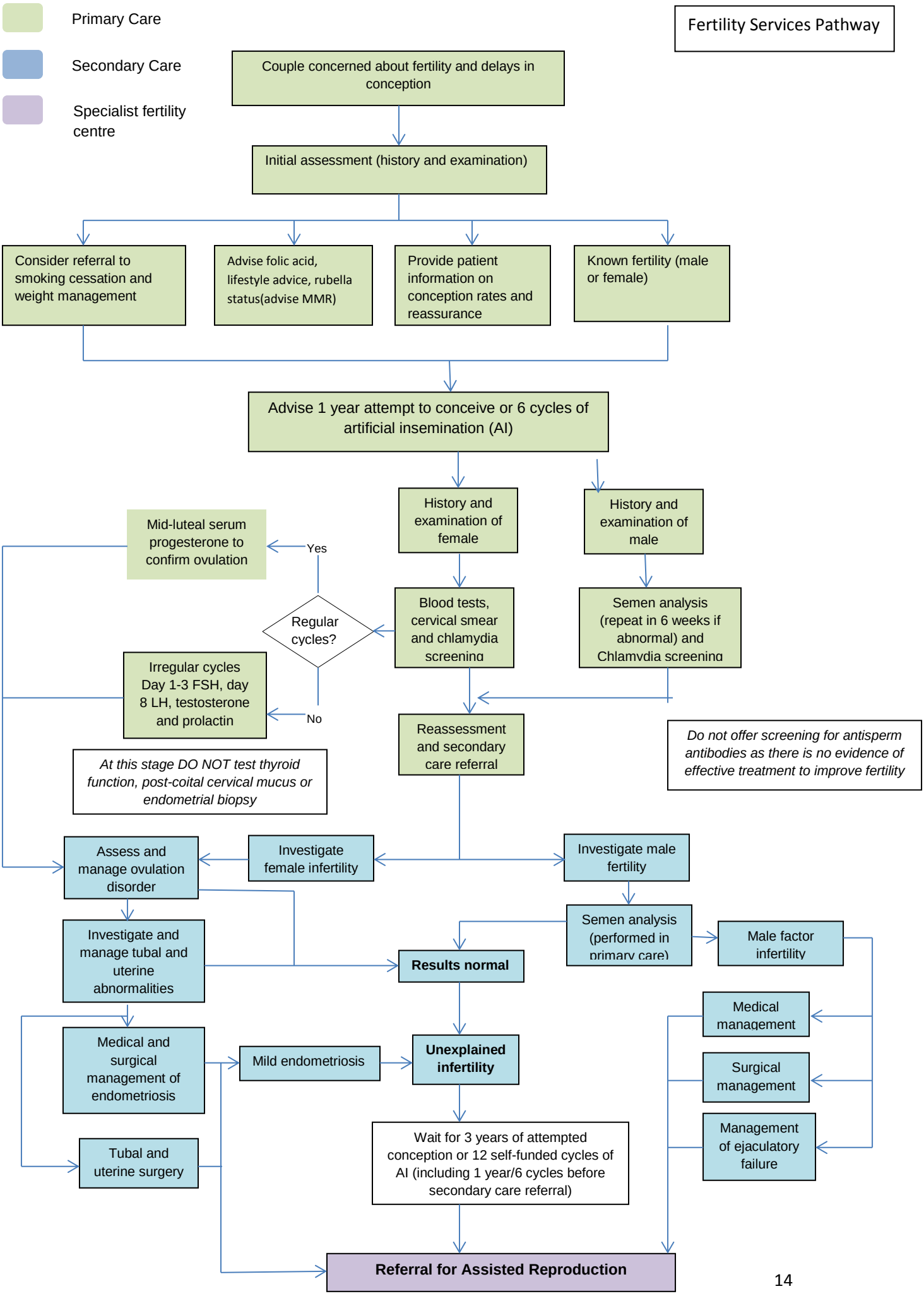
4.4 The patient pathway and a GP referral form can be found at the end of this document.

5 Access Criteria

No	Criterion	Description
1	Ovarian Reserve Testing, use one of the following: • FSH	To be eligible, the patient should have an FSH within 3 months of referral and on day 2 of the menstrual cycle of <9. For women, follicle-stimulating hormones (FSH) help to control and regulate the woman's menstrual cycle and is also partially responsible for the production of ova, or eggs, in the ovaries. If the FSH levels are either low or high, it is a clear indicator that something is out of balance within the reproductive system and may be causing issues with the couple being able to conceive.
2	Maternal age	Women aged 23 to 39 years at the start of super-ovulation (treatment) but where a woman reaches the age of 40 during treatment they will complete that cycle in the 40th year
3	Paternal Age	No paternal cut off age specified
4	Minimum / Maximum BMI	Between at least 19 and up to 30 for female and less than 35 for male. Patients outside of this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for management if required.
5	Duration of sub-fertility	Unexplained infertility for 3 years or more of regular intercourse or an equivalent 12 self-funded cycles of artificial insemination over a period of 3 years. There is no criterion for cases with a diagnosed cause of infertility.
6	Previous Fertility treatment for Women <40 years	The maximum number of embryo transfers, including fresh and frozen, is 2, with a maximum of 1 fresh cycles of assisted conception (IVF or IVF with ICSI if required and including sperm retrieval where indicated). Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS.
7	Previous fertility treatment for women ≥40 years	IVF for women aged 40 years and over will not be funded by the CCG

8	Smoking Status	Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment Where either of a couple smokes, only couples who agree to take part in a supportive and successful programme of smoking cessation with Carbon Monoxide verification as an evidence of non-smoking status. Will be accepted onto the IVF treatment waiting list.
9	Parental Status	Couples are ineligible for treatment if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.
10	Previous sterilisation	Ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.
11	Child Welfare	Providers must meet the statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born' and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.
12	Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document.
13	Residential Status	The couple should be registered with a GP member practice of NHS Southend CCG for at least 12 months
14	The cause of Infertility	In order to be eligible for treatment, Service users should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of 3 years. There is no criterion for couples with a diagnosed cause of infertility – see below: (a) Tubal damage, which includes: • Bilateral salpingectomy • Moderate or severe distortion not amenable to tubal surgery (b) Premature Menopause- amenorrhoea >6m and FSH >25 and aged <40 (c) Male factor infertility (d) Ovulation problems adequately treated but not successfully treated i.e no successful pregnancy achieved (e) Endometriosis where Specialist opinion is that IVF is the correct treatment (f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply)

15	The minimum investigations required prior to referral to the Tertiary centre are:	Female: • Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate • Rubella antibodies • Day 2 FSH. • Chlamydia screening • Hep B including core antibodies and Hep C and HIV status and core, within the last 3 months of treatment and repeated every 2 years. Male: • Preliminary Semen Analysis and appropriate investigations where abnormal (including genetics) • Hep B including core antibodies and Hep C, within the last 3 months and repeated after 2 years. • HIV status
16	Pre-implantation Genetic Diagnosis	PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.
17	Rubella Status	The woman must be rubella immune
18	IUI (Unstimulated)	As per NICE guidance 2013. Maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will only be offered under exceptional circumstances and an IFR application for funding must be made to the CCG.
19	Number of cycles of IVF	Women <40yrs who meet all eligibility criteria will be eligible for funding of one full cycle of IVF. If the woman reaches the age of 40 during treatment the cycle will be completed.
20	Waiting times	>3yrs Access to IVF will be available after three years of unexplained infertility. However, where there is a diagnosed cause of infertility, women will be eligible to access specialist fertility and IVF services immediately following secondary care assessment and investigation (after two years) rather than undergo additional waiting


Primary Care
Secondary Care
Specialist fertility centre
Fertility Services Pathway
Couple concerned about fertility and delays in conception
Initial assessment (history and examination)
Consider referral to smoking cessation and weight management
Advise folic acid, lifestyle advice, rubella status(advise MMR)
Provide patient information on conception rates and reassurance
Known fertility (male or female)
Advise 1 year attempt to conceive or 6 cycles of artificial insemination (AI)
History and examination of female
History and examination of male
Mid-luteal serum progesterone to confirm ovulation
Yes
Regular cycles?
Blood tests, cervical smear and chlamydia screening
Semen analysis (repeat in 6 weeks if abnormal) and Chlamydia screening
Irregular cycles Day 1-3 FSH, day 8 LH, testosterone and prolactin
No
Reassessment and secondary care referral
At this stage DO NOT test thyroid function, post-coital cervical mucus or endometrial biopsy
Do not offer screening for antisperm antibodies as there is no evidence of effective treatment to improve fertility
Assess and manage ovulation disorder
Investigate female infertility
Investigate male fertility
Investigate and manage tubal and uterine abnormalities
Semen analysis (performed in primary care)
Male factor infertility
Results normal
Medical management
Medical and surgical management of endometriosis
Mild endometriosis
Unexplained infertility
Surgical management
Management of ejaculatory failure
Tubal and uterine surgery
Wait for 3 years of attempted conception or 12 self-funded cycles of AI (including 1 year/6 cycles before secondary care referral)
Referral for Assisted Reproduction

NHS
Castle Point and Rochford
Clinical Commissioning Group

GP Referral Form for Fertility Assessment

EFFECTIVE FROM December 2014 – ALL NEW GP REFERRALS

Criteria for Referral for Assessment by Fertility Services:

1. In order to refer a couple for assessment all questions **MUST** be answered.

2. Please refer to your local CCG policy for details of eligibility criteria for assisted conception treatments including Intrauterine Insemination (IUI), Donor Insemination (DI), Oocyte Donation (OD) and in-vitro fertilisation (IVF).

If referring for IVF treatment, read eligibility criteria in policy (Specialist Fertility Services Commissioning Policy) prior to referral.

Patient Information			
Name:			
Address:		**DoB:**	
		NHS No:	
		Home Tel No:	
		Mobile No:	

To be completed by GP prior to referral to secondary care

Initial Lifestyle advice	**Tick**
Provide patient information on conception rates and reassurance	
Consider referral to smoking cessation and weight management	
Advise on alcohol intake and recreation drug use	
Recommend folic acid supplementation	
Other lifestyle advice (tight underwear, occupation)	

Failure to conceive after 1 year attempt or 6 cycles of artificial insemination - further investigations and consider referral to secondary care.

Investigations	**Date**	
Female		
Regular menstrual cycle	☐ YES	☐ NO
Serum FSH Level (Day 1-3)		
Serum LH Level (Day 8)		
Serum Progesterone at mid-luteal:		
Serum Prolactin:		
Serum Testosterone		
Male		
Semen Analysis: (if abnormal repeat in 6 weeks)		
Count		
Motility		
Morphology		

- **Assess and manage ovulation disorders appropriately and consider referral to secondary care at this stage**
- **Refer to secondary care for further investigations for suspected uterine and tubal abnormalities**
- **Refer for unexplained infertility if all hormonal profile and semen analysis normal**

Other investigations (if previous result available):

Investigations	Date	Results
Tubal Surgery		
Laparoscopy & Dye		
Hysteroscopy		
Hysterosalpingogram		
Ultrasound		

Other screening tests:

Screening				
Test	**Female**		**Male**	
	Date	**Result**	**Date**	**Result**
Chlamydia Screening				
Rubella				
Cervical Smear				

Referred by:

Signed:	Date:
Print Name:	
Contact Address:	
Email:	Telephone No: