

City and Hackney CCG Fertility policy Approved January 2015 (amended 1st Oct 2020 for COVID-19)

Introduction

City and Hackney CCG is responsible for commissioning a range of health services including hospital, mental health and community services for the local population. The CCG has a statutory duty to maintain financial balance, which means that it must make judgements about the affordability of any proposed service for local patients.

This clinical policy is intended to support individuals and couples who want to have a baby, but who have a clinical problem which means that they are potentially infertile. The CCG's aim through this policy is to offer the opportunity to have a baby to as many patients as possible within the context of its overall financial position.

This policy has been developed following discussions with stakeholders, including local GPs and lead clinicians from fertility units in local hospitals. In developing this policy, the CCG has also considered and adopted relevant NICE guidance wherever feasible. However, the need to balance service access demands with affordability has meant that in some sections the policy varies from the full recommendations made by NICE.

The relevant NICE Clinical Guidance 156, Fertility can be accessed here: <http://www.nice.org.uk/guidance/CG156>

Individual Funding Requests

This policy cannot anticipate every possible individual clinical presentation. Clinicians are invited to submit Individual Funding Requests for patients who they consider to have exceptional clinical circumstances and whose needs are not fully addressed by this policy. The CCG will consider such requests in accordance with its policy on Individual Funding Requests.

Eligibility criteria

Couples will **only** be referred for assisted conception if they meet the eligibility criteria below and when **all** appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE guidelines.

Patients accessing IVF should be fully informed of likely success rates and alternative approaches to parenting, including fostering and adoption.

COVID-19 – Temporary variation to agree criteria for IVF in North East London infertility policies

From the 1st October 2020, the City and Hackney Fertility Policy is amended as below to ensure women are not disadvantaged by the pause in services as a result of COVID-19. All other parts of the policy remain unchanged.

Previous Eligibility Criteria	Temporary Eligibility Criteria
<ul style="list-style-type: none"> • IVF is offered to women aged under 42 years old. Women should be referred so that they can commence a treatment cycle before their 42nd birthday. • Women aged 40-41 will only be offered treatment if they have never previously had IVF treatment (however funded) • Women aged 40-41 shall be eligible only for one full cycle of IVF including the implantation of fresh and frozen embryos/ blastocysts from a single course of ovarian stimulation 	<ul style="list-style-type: none"> • IVF is offered to women aged under 43 years old. Women should be referred so that they can commence a treatment cycle before their 43rd birthday. • Women aged 40-42 will only be offered treatment if they have never previously had IVF treatment (however funded) • Women aged 40-42 shall be eligible only for one full cycle of IVF including the implantation of fresh and frozen embryos/ blastocysts from a single course of ovarian stimulation

NOTE: The CCG only commissions Fertility/IVF treatments from the following providers:

1. The Homerton University Hospital Trust
2. Barts Health Trust
3. Guys and St Thomas's Hospital Trust

Please do not refer to other providers as these are not funded to provide fertility treatments

1. Definition of a treatment cycle	For the purposes of this policy, an IVF cycle will be defined as the process which starts with ovulation stimulation and ends with the implantation of either a fresh embryo/ blastocyst or the implantation of a frozen embryo/ blastocyst.
2. GP registration status	Patient should be registered on the medical list of City and Hackney CCG.
3. Age of the female patient	<p>IVF is offered to women aged under 42 years old. Women should be referred so that they can commence a treatment cycle before their 42nd birthday.</p> <p>Women aged 40-41 will only be offered treatment if they have never previously had IVF treatment (however funded).</p> <p>Women aged 40-41 shall be eligible only for one full cycle of IVF including the implantation of fresh and frozen embryos/ blastocysts from a single course of ovarian stimulation.</p> <p>For all women, first treatment cycles must be commenced before the woman's 42nd birthday. Second treatment cycles must be commenced before the woman's 40th birthday.</p> <p>Referring clinicians should be aware of the work up time required by the providing trusts, and ensure that referrals are made in time for women to start their first treatment cycle before their 42nd birthday.</p>
4. Life style factors	<p>The woman must have a body mass index (BMI) of between 19 and 30 at the time commencement of treatment.</p> <p>Patients must be non-smokers in order to access any fertility treatment and continue to be non-smokers throughout treatment.</p>
5. Children from previous relationship	<p>IVF will not be offered to couples who have a child together or single applicants who already have a child.</p> <p>IVF will be offered to couples where one of the partners has a child from a previous relationship, but the other does not. Both partners must confirm they have NOT previously undergone a sterilisation procedure.</p> <p>Foster children are not included in these restrictions.</p>

Number of cycles funded	
<p>NICE guidance argues that there is limited evidence for continuing to offer IVF to women who do not achieve pregnancy beyond a third cycle of fresh/ frozen embryo transfer. The guidance recommends that all cycles, whether funded by the NHS or privately be considered. The CCG therefore, will not fund additional treatment to a patient who has already had three fresh cycles of IVF.</p>	
<p>6. Number of cycles to be funded for women aged up to 39 years old who have previously had no more than one cycle of ovarian stimulation leading to an embryo transfer</p>	<p>City and Hackney CCG will support patients to have a maximum of three opportunities to become pregnant using either fresh or frozen embryos.</p> <p>Funded treatment could therefore comprise:</p> <ul style="list-style-type: none"> • Three fresh embryo transfers, and none frozen • Two fresh embryo transfers, and one frozen • One fresh embryo transfer, and two frozen
<p>6.1. Number of cycles to be funded for women aged up to 39 years old who have previously had two cycles of ovarian stimulation leading to an embryo transfer</p>	<p>For women who have previously had two cycles of ovarian stimulation leading to embryo transfer the CCG will fund for them to have a further single fresh and frozen embryo transfer.</p>
<p>6.1 Number of cycles to be funded for women aged 40 to 41 years old</p>	<p>Women aged 40-41 years old will be offered a maximum of one fresh embryo transfer and one frozen embryo transfer, provided they have not previously undertaken IVF.</p>
<p>7. Cancelled and Abandoned cycles</p>	<p>NICE guidelines define a cancelled cycle as occurring when egg collection is not undertaken following ovarian stimulation.</p> <p>An abandoned cycle is not defined by NICE but is defined by this policy as including treatment leading to a failed embryo transfer.</p> <p>Occasionally there may be good clinical or non-clinical reasons why a cycle needs to be cancelled or abandoned. For this reason the first two abandoned/ cancelled cycles will not count towards the total number of funded cycles in section 6 above.</p>

Treatment Pathway

This policy is intended, as per NICE guidance, for people who have a possible pathological problem (physical or psychological) to explain their infertility.

City and Hackney CCG will fund investigation and treatment for all individuals and couples provided there is evidence of subfertility.

The process for demonstrating subfertility will necessarily be different for heterosexual couples than for same sex couples or singletons and these differences are reflected in the sub clauses below

8. Subfertility Heterosexual couples	<p>Individuals/couples with a known cause of infertility should be referred without delay for appropriate assisted conception assessment.</p> <p>Women who have not become pregnant after one year of regular unprotected vaginal intercourse two to three times per week should be referred with their partner for further assessment and possible treatment.</p> <p>If the woman is aged 36 or over then such assessment should be considered after 6 months of unprotected regular intercourse.</p> <p>If a cause for infertility is found, the individual should be referred for appropriate treatment without further delay.</p> <p>IVF treatment can be offered to women with unexplained infertility who have not conceived after 2 years (this can include up to 1 year before their fertility investigations) of regular unprotected sexual intercourse (or 12 months for women aged 36 and over).</p>
8.1 Subfertility pathway Same sex female couples and single women	<p>Female same sex couples and single women who have not become pregnant after 6 cycles of IUI undertaken in a clinical setting should be referred for further assessment and possible treatment.</p> <p>If a cause for the infertility is found, the individual should be referred for appropriate treatment without further delay.</p> <p>Where no cause of infertility can be identified women should be offered access to assisted conception if they have subfertility demonstrated by a further 6 cycles of IUI (12 in total)</p> <p>If the woman is aged 36 or over then such assessment should be considered after 6 cycles of IUI.</p> <p>As per section 9 below, the CCG will not routinely fund the IUI cycles described above.</p> <p>As per section 14 below, the CCG will not routinely fund the use of donated sperm used in the IUI cycles described above</p>
8.2 Same sex male couples and single men	<p>Male same sex couples and single men will be referred for infertility investigation if no pregnancy results following six cycles of IUI for which the man's donated sperm has been used.</p>

<p>9.</p> <p>Intra Uterine Insemination (IUI)</p>	<p>City and Hackney CCG will not routinely fund the use of unstimulated IUI.</p> <p>IUI will, however, be offered as a treatment option for the following groups as an alternative to vaginal sexual intercourse:</p> <ul style="list-style-type: none"> • 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) <p>As per section 14 below, whilst paying for the IUI procedure, City and Hackney CCG will not fund the use of donor sperm.</p> <p>A woman who has not become pregnant following 6 cycles of IUI carried out within a clinical setting should be referred for further assessment and appropriate treatment for infertility.</p>
<p>10.</p> <p>Ovarian reserve testing</p>	<p>Low Ovarian Reserve</p> <p>Women with low ovarian reserve are less likely to achieve pregnancy through IVF.</p> <p>Women referred for IVF assessment shall be offered an ovarian reserve test as per NICE guidance to identify and exclude those with low chance of conception.</p> <p>NICE guidance describes three tests which may be used:</p> <ul style="list-style-type: none"> • Total Antral Follicle count(AFC) • Anti-Müllerian hormone (AMH) • Follicle-stimulating hormone (FSH) <p>City and Hackney CCG will fund IVF only for women who have demonstrated that they have sufficient ovarian reserve on one of these three tests described in the NICE fertility guidance.</p> <p>This means that the patient must have either:</p> <ul style="list-style-type: none"> • Total antral follicle count (AFC) of greater than 4 Or • Anti-Müllerian hormone (AMH) of greater than 5.4 pmol/l Or • Follicle-stimulating hormone (FSH) less than 8.9 IU/l <p>Ovarian reserve testing should only be conducted within the overall context of a fertility assessment carried out by a specialist centre.</p> <p>GPs should not order these tests prior to referral to a Fertility Unit.</p>

<p>11.</p> <p>Number of embryos to be transferred - “One Child at a Time”</p>	<p>City and Hackney CCG will require provider Trusts to adhere with the HFEA multiple birth restriction strategy.</p> <p>Provider Trusts will be expected to counsel patients about the risks associated with multiple births, and advise them that they will receive a single embryo/blastocyst transfer unless there is a clear clinical justification for not doing so.</p>
<p>12.</p> <p>Fertility Preservation</p>	<p>City and Hackney CCG will fund the collection and storage of eggs, embryos and sperm for individuals with cancer or other illnesses which may impact on their future fertility with the following conditions:</p> <ul style="list-style-type: none"> • City and Hackney CCG will fund the storage for first five years only. • City and Hackney CCG will not fund for the continued storage of eggs/embryos for a woman aged over 42 • City and Hackney CCG will not fund for the storage of sperm for a man aged over 55. <p>The eligibility criteria set out in this policy must be applied to any subsequent use of the stored material.</p>
<p>13.</p> <p>Egg Donation</p>	<p>City and Hackney CCG will not fund the use of donated eggs but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy.</p> <p>Patients wishing to use donor eggs treatments must make their own arrangements to access these and are advised to check with the treating provider unit to ensure compliance with best practice guidelines.</p>
<p>14.</p> <p>Sperm Donation</p>	<p>City and Hackney CCG will not fund the purchase of donor sperm but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy.</p> <p>Patients wishing to access donor sperm treatments must make their own arrangements to access these and advised to check with the treating provider unit to ensure compliance with best practice guidelines.</p>
<p>15.</p> <p>Reversal of sterilisation Surgical sperm retrieval/</p>	<p>City and Hackney CCG will not fund treatment for couples where subfertility is the result of a sterilisation procedure in either partner.</p> <p>City and Hackney CCG will not fund the surgical reversal of either male or female sterilisation</p> <p>City and Hackney CCG will not fund treatment where sub fertility remains after a reversal of sterilization treatment.</p> <p>Surgical sperm retrieval will be funded in appropriately selected patients, provided that the azoospermia is not the result of a sterilisation procedure.</p>

16. Sperm Washing	City and Hackney CCG will fund sperm washing for IUI/IVF/ICSI for couples where the male partner is HIV positive and the female partner is HIV negative in order to prevent the transmission of HIV to an unborn child.
17. Surrogacy	IVF using a surrogate mother will not be funded by City and Hackney CCG.