

**Blackburn with Darwen Clinical Commissioning Group**

**Policies for the Commissioning of Healthcare**

**Policy for Assisted Conception Services**

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
<b>1</b>	<b>Policy Criteria</b>
<b>1.1</b>	The CCG will commission one treatment unit of assisted conception (as defined in section 1.2) provided <b>all</b> of the following criteria are satisfied at the date on which the treatment unit commences:
<b>1.1.1</b>	<ul style="list-style-type: none"> <li>• Clinical infertility, as described in 1.3, has been demonstrated;</li> </ul>
<b>1.1.2</b>	<ul style="list-style-type: none"> <li>• The patient/s have no living biological or adopted children from the current or any previous relationship;</li> </ul>
<b>1.1.3</b>	<ul style="list-style-type: none"> <li>• Neither partner has previously had a treatment unit or part of a treatment unit of assisted conception irrespective of the source of funding of that treatment unit, unless it can be clearly demonstrated that:             <ul style="list-style-type: none"> <li>• The unit of treatment was undertaken in line with section 1.3 to demonstrate the presence of clinical infertility OR</li> <li>• The unit of treatment was in a different relationship AND EITHER</li> <li>• The cause of the infertility was attributable predominantly to the other partner in that relationship OR;</li> <li>• The treatment was not related to clinical infertility;</li> </ul> </li> </ul>
<b>1.1.3.1</b>	
<b>1.1.3.2</b>	
<b>1.1.3.3</b>	
<b>1.1.3.4</b>	
<b>1.1.4</b>	<ul style="list-style-type: none"> <li>• The female partner is between 18 years and 42 years of age. Treatment must commence before the female partners 43<sup>rd</sup> birthday;</li> </ul>
<b>1.1.5</b>	<ul style="list-style-type: none"> <li>• Additionally, if the funding package includes harvesting of eggs from a donor, then the donor has not yet reached the age of 40 years and has no evidence of infertility;</li> </ul>
<b>1.1.6</b>	<ul style="list-style-type: none"> <li>• Neither partner has been previously sterilised;</li> </ul>
<b>1.1.7</b>	<ul style="list-style-type: none"> <li>• The female partner seeking to become pregnant has a body mass index in the range 19-30;</li> </ul>
<b>1.1.8</b>	<ul style="list-style-type: none"> <li>• The female partner is a non-smoker and commits to remain so</li> </ul>

<p>1.1.9</p> <p>1.1.10</p> <p>1.1.11</p> <p>1.1.11.1</p>	<p>throughout the treatment unit and until the completion of any resulting pregnancy; For the purposes of this policy the use of an e-cigarette is considered equivalent to non-smoking status.</p> <ul style="list-style-type: none"> <li>• The other partner (when applicable), is a non-smoker, and commits to remain so throughout the treatment unit; for the purposes of this policy the use of an e-cigarette is considered equivalent to non-smoking status.</li> <li>• If the female partner is aged 40-42, a treatment unit will be offered provided the following two additional criteria are fulfilled (NICE CG 156, {1.11.1.4}): <ul style="list-style-type: none"> <li>• There is no evidence of low ovarian reserve (see Appendix 1 for definition);</li> <li>• There has been a discussion of the additional implications of pregnancy and IVF at this age.</li> </ul> </li> </ul>
<b>1.2</b>	<b>Treatment Unit</b>
<p>1.2.1</p> <p>1.2.2</p> <p>1.2.2.1</p> <p>1.2.2.2</p>	<p>A treatment unit is the currency used to describe the amount of assisted conception treatment to which a patient is eligible.</p> <p>A treatment unit is defined as EITHER:</p> <p>A - Up to 12 separate attempts at IUI, each in a different menstrual cycle;</p> <p style="text-align: center;"><b>OR</b></p> <p>B - One programme of IVF treatment comprising:</p> <ul style="list-style-type: none"> <li>• Ovarian Stimulation;</li> <li>• Induction of ovulation;</li> <li>• Harvesting of resultant eggs;</li> <li>• Harvesting of semen;</li> <li>• Fertilisation;</li> <li>• Storage of eggs/ semen/ embryos in accordance with section 1.5;</li> </ul> <p>Transfer of any resultant fresh and frozen embryo(s) on as many separate occasions as required until either, a pregnancy leading to a live birth is achieved or there are no embryos remaining.</p>
<p>1.2.3</p>	<p>The CCG will define a unit as cancelled if it fails to reach the stage of an attempt to harvest eggs.</p> <p>For the purposes of this policy a unit will be counted as cancelled on only one occasion in the lifetime of a woman. Otherwise if a unit has been partially completed it will count as a whole unit for the purposes of calculating future eligibility for assisted conception services.</p> <p>If a unit is cancelled due to low ovarian reserve this should be taken into</p>

	account when considering suitability for further IVF treatment.
<b>1.2.4</b>	In the event of a treatment unit failing as a result of an error within the service provider the CCG expects the service provider to offer a repeat treatment unit. The failed treatment unit will not count towards the woman's lifetime allowance as such a failed unit does not give any indication of the probability of future success.
<b>1.2.5</b>	IUI is likely to be offered using the partners' own gametes only when either; it is impossible for them to have sexual intercourse, or when the sperm has been frozen in accordance with the criteria in this policy and the couple are now eligible for assisted conception services.
<b>1.3</b>	<b>Clinical Infertility</b>
<b>1.3.1</b>	For the purposes of this policy, a person/couple are considered to be clinically infertile where they are of reproductive age and either:
<b>1.3.1.1</b>	<ul style="list-style-type: none"> <li>• There is a diagnosed condition or congenital abnormality that would make natural conception impossible; <b>or</b></li> </ul>
<b>1.3.1.2</b>	<ul style="list-style-type: none"> <li>• There is a known cause of infertility, following assessment and investigation in the circumstances set out in 1.3.2; <b>or</b></li> </ul>
<b>1.3.1.3</b>	<ul style="list-style-type: none"> <li>• There is no known cause of infertility and the criteria outlined at 1.3.3 are met; <b>or</b></li> </ul>
<b>1.3.1.4</b>	<ul style="list-style-type: none"> <li>• There is an inability to have sexual intercourse and the criteria outlined at 1.3.4 are met.</li> </ul>
<b>1.3.2</b>	A person/couple should be offered further clinical assessment and investigation if they are of reproductive age and have not conceived after:
<b>1.3.2.1</b>	<ul style="list-style-type: none"> <li>• 1 year of regular (i.e. 2-3 times per week) unprotected vaginal sexual intercourse with the same partner; <b>or</b></li> </ul>
<b>1.3.2.2</b>	<ul style="list-style-type: none"> <li>• 6 cycles of artificial insemination (with partner or donor sperm).</li> </ul>
<b>1.3.2.3</b>	Where conception is attempted via vaginal sexual intercourse or artificial insemination with partner sperm, the partner should also be offered assessment and investigation.
<b>1.3.3</b>	Where there is no known cause of infertility to fulfil the criteria at section 1.3.1.3 a person/couple must have:
<b>1.3.3.1</b>	<ul style="list-style-type: none"> <li>• undergone assessment and investigation in the circumstances set out in 1.3.2; and</li> </ul>
<b>1.3.3.2</b>	<ul style="list-style-type: none"> <li>• failed to conceive after a total of either:</li> </ul>
<b>1.3.3.2.1</b>	<ul style="list-style-type: none"> <li>- 2 years of regular (i.e. 2 – 3 times per week) unprotected vaginal sexual intercourse with the same partner; <b>or</b></li> </ul>
<b>1.3.3.2.2</b>	<ul style="list-style-type: none"> <li>- 12 cycles of self-funded artificial insemination (with either partner or donor sperm), at least 6 of which are by intrauterine insemination undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic.</li> </ul>

<b>1.3.4</b>	The CCG will regard an inability to have sexual intercourse as being equivalent to clinical infertility, and will commission one treatment unit (as defined in section 1.2), under any of the following circumstances:
	<b>EITHER</b>
<b>1.3.4.1</b>	<ul style="list-style-type: none"> <li>• There is a structural abnormality of the genital organs such that sexual intercourse would be impossible;</li> </ul>
	<b>OR</b>
<b>1.3.4.2</b>	<ul style="list-style-type: none"> <li>• There is a serious psychosexual problem. The patient has seen a senior clinical psychologist who advises that the problem is pathological and cannot be reversed and supports the use of IUI;</li> </ul>
	<b>AND</b>
<b>1.3.4.2.1</b>	<ul style="list-style-type: none"> <li>• The psychosexual problem leads to a physical obstacle to sexual intercourse, e.g. erectile or ejaculatory failure or vaginismus.</li> </ul>
	<b>OR</b>
<b>1.3.4.3</b>	<ul style="list-style-type: none"> <li>• There is a physical disability that would make sexual intercourse impossible or extremely painful, or which would risk causing significant injury to one of the partners;</li> </ul>
	<b>AND</b>
<b>1.3.4.3.1</b>	<ul style="list-style-type: none"> <li>• The gynaecologist responsible for delivering the IUI advises that the feature making sexual intercourse impossible, extremely painful, or which would risk causing significant injury to one of the partners would not mean that pregnancy or delivery would be clinically inadvisable, for either the mother or the child;</li> </ul>
	<b>OR</b>
<b>1.3.4.3.2</b>	<ul style="list-style-type: none"> <li>• There is irreversible erectile dysfunction associated with a clinical condition reasonably assumed to be causal (e.g. diabetes, multiple sclerosis, spinal cord dysfunction).</li> </ul>
<b>1.4</b>	<b>Sperm and Egg Donation</b>
<b>1.4.1</b>	Sperm and egg donation will be funded if:
<b>1.4.1.1</b>	<ul style="list-style-type: none"> <li>• it is required as part of an approved treatment unit <b>and</b></li> </ul>
<b>1.4.1.2</b>	<ul style="list-style-type: none"> <li>• the eligibility criteria at section 1 of the policy are fulfilled <b>and</b></li> </ul>
<b>1.4.1.3</b>	<ul style="list-style-type: none"> <li>• the patient, or for couples one of the partners, is able to make a contribution to the child's genome.</li> </ul>
<b>1.4.1.4</b>	Assisted conception to create an embryo entirely from third party gametes will not be funded.
<b>1.4.2</b>	Where there is a lack of donor eggs available patients who are eligible for treatment with donor eggs, in line with NICE recommendations, will be placed on a hospital waiting list, where these exist. Patients will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. Funding is dependent on the patient fulfilling the eligibility criteria at section 1 of the policy at the time treatment commences.

<b>1.5</b>	<b>Embryo, Egg and Sperm Storage</b>
<b>1.5.1</b>	<b>The storage of gametes or embryos when assisted conception procedures produce more gametes or embryos than can be used immediately</b>
<b>1.5.1.1</b>	The CCG <b>will</b> fund the freezing and storage of surplus eggs or embryos where assisted conception treatments have produced more eggs or embryos than can be used for immediate transfer to the uterus. However, eligibility for funding for ongoing storage will only be provided in line with section 1.5 of this policy.
<b>1.5.1.2</b>	The CCG will not provide funding for the storage of surplus sperm / semen except in accordance with sections 1.5.2 below.
<b>1.5.2</b>	<b>The storage of gametes or embryos for the purposes of fertility preservation</b>
<b>1.5.2.1</b>	The CCG <b>will</b> commission the harvesting and storage of gametes for patients who are on the cancer pathway, such that clinical advice is that treatment is required immediately, that will remove or irreversibly damage the gonads or may prevent the production of gametes.
<b>1.5.2.2</b>	The CCG will commission the storage of gametes when they have been retrieved for the purposes of fertility preservation as part of an established NHS pathway of care.
<b>1.5.2.3</b>	The CCG will commission the harvesting and storage of gametes for patients who have been diagnosed with gender dysphoria, are under the care of a Specialist Gender Identity Centre (GIC) and are likely to develop infertility as an unwanted consequence of the treatment required to address their condition.
<b>1.5.2.4</b>	In circumstances described in 1.5.2.1, 1.5.2.2 and 1.5.2.3 the CCG will not apply the eligibility criteria described in 1.1, with the exception of the upper age limit restriction for female partners, in line with the principle of effectiveness. However, by funding the storage of gametes the CCG is NOT agreeing to fund further, future assisted conception services.  If gametes are stored for the purpose of fertility preservation and assisted conception treatment is required, in order to be eligible for assisted conception treatment the patient will need to demonstrate eligibility in line with the criteria at section 1.1 of this policy, or any relevant policy in force at the time.

<b>1.5.2.5</b>	The CCG will not commission the harvesting and storage of gametes for patients with a level of risk of future infertility in accordance with the Principle of Appropriateness.
<b>1.5.2.6</b>	The CCG will not commission the harvesting and storage of eggs for women with low ovarian reserve in accordance with the Principle of Effectiveness.
<b>1.5.3</b>	<b>Duration of embryo or gamete storage</b>
<b>1.5.3.1</b>	Funding for storage of gametes or embryos will continue until one of the following occurs:
<b>1.5.3.1.1</b>	<ul style="list-style-type: none"> <li>• The gamete or embryo has been in storage for two years;</li> </ul>
<b>1.5.3.1.2</b>	<ul style="list-style-type: none"> <li>• In cases where the storage has occurred in line with section 1.5.2.1-1.5.2.3 above, embryo or gamete preservation should be offered for an initial period of ten years in line with NICE CG 156 guidance, rather than the two years stipulated at 1.5.3.1.1. However, the criteria at 1.5.3.1.1 will apply once the patient has commenced treatment on the assisted conception pathway;</li> </ul>
<b>1.5.3.1.3</b>	<ul style="list-style-type: none"> <li>• The patient / couple have had a live birth and now have a living child who has reached the age of one year. (see section 1.5.3.3)</li> </ul>
<b>1.5.3.1.4</b>	<ul style="list-style-type: none"> <li>• The female partner dies.</li> </ul>
<b>1.5.3.2</b>	The CCG expects the service provider to give the patient at least six months' notice that NHS funding for the storage will cease, and this will be built into the service agreement. The CCG expects the Trust to give the patients the option of continuing to fund the storage beyond the point at which CCG funding ceases. No embryos or gametes stored under funding by the CCG should be destroyed without giving the patients the opportunity to consider private funding or donation.
<b>1.5.3.3</b>	The purpose of funding storage for gametes or embryos after a live birth is only to enable the patient to decide what to do with them, and does not imply that funding will be offered for the use of those gametes or embryos to attempt to achieve a pregnancy.
<b>1.6</b>	<b>Surrogacy</b>
<b>1.6.1</b>	The CCG will not commission any form of assisted conception services or treatment leading to surrogacy for those in surrogacy arrangements. (i.e. the use of a third party to bear a child for another couple). This is because of the numerous legal and ethical issues involved. See also sections 3.5 and 6.4.
<b>1.7</b>	<b>Treatment following Reversal of Sterilisation</b>
<b>1.7.1</b>	Assisted conception services will not be provided where this is required due to a previous sterilisation procedure or a reversal of sterilisation procedure in

1.7.2	either partner in accordance with the Principle of Appropriateness. The CCG will commission assisted conception services for the management of azoospermia, provided the cause of the azoospermia is unrelated to a previous vasectomy.
1.8	<b>Uterine Transplantation</b>
1.8.1	The CCG will not commission uterine transplantation, and neither will it commission assisted conception services when the intention is that the pregnancy will be carried in a transplanted uterus in accordance with the Principle of Cost Effectiveness.
1.9	<b>Where responsibility lies with more than one CCG</b>
1.9.1	When assisted conception services involve biological participants who are the responsibility of more than one CCG, this CCG will follow any mandatory requirement in terms of the split of funding. In the absence of a mandatory requirement, the CCG expects that the funding responsibility will be shared equally between the CCGs responsible for the female partner and the other partner who seek to benefit from the service.
1.10	<b>NICE Guidance</b>
1.10.1	Except where indicated otherwise in this policy:
1.10.1.1	<ul style="list-style-type: none"> <li>The CCG expects to commission assisted conception services in accordance with NICE technology appraisal guidance or NICE clinical guidance that may be in force at the time, and;</li> </ul>
1.10.1.2	<ul style="list-style-type: none"> <li>The CCG expects its service providers to deliver assisted conception services in accordance with NICE technology appraisal guidance or NICE clinical guidance that may be in force at the time.</li> </ul>
1.11	<b>Service Providers</b>
1.11.1	The CCG will commission services that fall within the scope of this policy only when they are offered by service providers within its portfolio of service agreements or are available on the Free Choice Network in line with the General Policy for IFR Decision Making.
1.12	<ul style="list-style-type: none"> <li>In all respects the CCG will comply with legal requirements which take precedence over other provisions of this policy.</li> </ul>
2	<b>Scope and Definitions</b>
2.1	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Assisted Conception is a group of clinical procedures intended to achieve a

	healthy pregnancy and involving the temporary removal of gametes (eggs and / or sperm) from the human body.
<b>2.3</b>	<ul style="list-style-type: none"> <li>The scope of this policy is limited to the commissioning of tertiary fertility services and includes intra-uterine insemination (IUI), intracytoplasmic sperm injection (ICSI) and in vitro fertilisation (IVF). This may also include the provision of donor sperm and donor eggs and the storage of gametes and embryos.</li> </ul> <p>The groups included are limited to:</p> <ul style="list-style-type: none"> <li>People who have vaginal intercourse;</li> <li>Specific patient subgroups (as listed in NICE CG 156 guideline scope): <ul style="list-style-type: none"> <li>Women in same-sex relationships who have unexplained infertility after donor insemination;</li> <li>Single women who have unexplained infertility after donor insemination;</li> <li>People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychological problem;</li> <li>People with conditions or disabilities that require specific consideration in relation to methods of conception;</li> <li>People who are preparing for cancer treatment who may wish to preserve their fertility.</li> </ul> </li> </ul> <p>The scope of this policy also includes requests for assisted conception for:</p> <ul style="list-style-type: none"> <li>Those who have undergone a sterilisation procedure or a reversal of sterilisation procedure;</li> <li>Those who wish to use surrogacy arrangements;</li> <li>Those who wish to consider uterine transplantation.</li> </ul>
<b>2.3.1.</b>	
<b>2.3.2</b>	
<b>2.3.2.1</b>	
<b>2.3.2.2</b>	
<b>2.3.2.3</b>	
<b>2.3.2.4</b>	
<b>2.3.2.5</b>	
<b>2.3.3</b>	
<b>2.3.3.1</b>	
<b>2.3.3.2</b>	
<b>2.3.3.1</b>	
<b>2.4</b>	The following are not within the scope of this policy:
<b>2.4.1</b>	<ul style="list-style-type: none"> <li>Investigations to ascertain the cause of infertility;</li> </ul>
<b>2.4.2</b>	<ul style="list-style-type: none"> <li>The prescribing or administration of medicines to improve fertility by increasing the probability of natural conception;</li> </ul>
<b>2.4.3</b>	<ul style="list-style-type: none"> <li>Pre-implantation genetic diagnosis (except that a policy for PIGD may make reference to aspects of this policy);</li> </ul>
<b>2.4.4</b>	<ul style="list-style-type: none"> <li>Services to address recurrent miscarriage;</li> </ul>
<b>2.4.5</b>	<ul style="list-style-type: none"> <li>Reversal of sterilisation as a service for the purpose of alleviating post-vasectomy pain.</li> </ul>
<b>2.4.6</b>	<ul style="list-style-type: none"> <li>Surgical sperm retrieval (this intervention is the commissioning responsibility of NHS England via the Highly Specialised Adult Urology services.)</li> </ul>
<b>2.5</b>	The CCG recognises that a patient may have certain features, such as:
<b>2.5.1</b>	<ul style="list-style-type: none"> <li>No children;</li> </ul>
<b>2.5.2</b>	<ul style="list-style-type: none"> <li>Difficulty in conceiving;</li> </ul>



2.5.3 2.5.4 2.5.5 2.5.6 2.5.7  2.5.8  2.5.6	<ul style="list-style-type: none"> <li>• A diagnosis that implies that it may be difficult to conceive;</li> <li>• A risk of becoming unable to conceive in future;</li> <li>• Gametes or embryos in storage;</li> <li>• A blood-borne or sexually transmissible infection;</li> <li>• Previous failed attempts at assisted conception (including attempts that resulted in a conclusion that future attempts would be done differently);</li> <li>• A wish to use services within the scope of this policy.</li> </ul> <p>Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.</p>
2.6	Appendix 1 defines and explains certain terms and abbreviations that are used in this policy.
2.7	The CCG is committed to eliminating discrimination and promoting equality in its own policies, practices, and procedures. While no protected characteristic under the Equality Act is automatically a matter for exceptionality under this policy, the CCG is committed to treating everyone equally and with the same attention, courtesy and respect regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation.
<b>3</b>	<b>Appropriate Healthcare</b>
3.1	The purpose of assisted conception services is to enable people who are otherwise clinically unable to do so, to achieve a pregnancy leading to a live birth. The CCG considers that assisted conception to achieve this purpose will accord with the Principle of Appropriateness.
3.2	The CCG is aware that most children are conceived as a result of a natural process that takes place without any clinical intervention. The CCG recognises the need to ensure that any active intervention it makes in relation to this natural process should comply with the provisions of the Equality Act (2010).
3.3  3.3.1  3.3.2 3.3.3	<p>The CCG considers that other services competing for the same CCG resource more clearly have a purpose of preserving life or of preventing grave health consequences. Therefore, the CCG has committed only a limited budget to assisted conception services and sets the following policy criteria which rely on the Principle of Appropriateness:</p> <ul style="list-style-type: none"> <li>• The criteria requiring a health problem to be demonstrated, thus confirming that conception will not occur without an assisted conception intervention;</li> <li>• The criteria relating to previous children</li> <li>• The criteria relating to reversal of sterilisation, recognising that sterilisation is usually carried out as a matter of choice and not as a matter of clinical need.</li> </ul>
3.4	Most requests for consideration under this policy will be from heterosexual

	<p>couples who request assisted conception services using their own gametes to conceive a pregnancy in the female partner. There may be other circumstances in which the request for funding comes from an individual or individuals who are not in a heterosexual relationship, or in which the circumstances of the couple mean that assisted conception would need to involve a third party. Decisions in such cases will rely on the Principle of Appropriateness and also on the CCG's position in relation to third party involvement which is within scope of the Principle of Ethics.</p>
<b>3.5</b>	<p>The CCG considers that its portfolio of service agreements contains a range of services that will address the needs of the majority of patients with clinical infertility who request assisted conception services. The CCG considers it appropriate to focus its resources on that range of services.</p> <p>Therefore, the CCG will not normally commission services of an unusual, innovative or highly specialised nature, and this relies partly or wholly on the Principle of Appropriateness. An example of this is the policy statements in respect of services not offered by service providers within its portfolio of service agreements, and also to services such as surrogacy and uterine transplantation.</p>
<b>3.6</b>	<p>The CCG intends that the benefit of assisted conception to the patient is from achieving parental status in respect of a child to whom the patient has made a genetic contribution. The experience of pregnancy, breast feeding, or associated bonding, is not the primary purpose of the service. Therefore, if it is not possible for the patient (either or both partners) to make a contribution to the child's genome, then assisted conception to create an embryo entirely from third party gametes is not appropriate. Some patients in this situation may seek adoption or fostering. Assisted conception is not appropriate for the purpose of rectifying a deficit in the availability of children for adoption or fostering, and therefore unavailability of children will not normally provide grounds for exceptionality in this respect.</p>
<b>3.7</b>	<p>Although the age limit for treatment relies mainly on the Principle of Effectiveness, the purpose of this policy is to restore fertility to people who, without their medical conditions would have good fertility. The lower chance of natural conception in a population of normal older women (compared with a population of normal younger women) is itself a reason why this policy does not offer assisted conception services (irrespective of whether they use their own or donated eggs) to women older than the levels set in NICE guidance (CG156).</p> <p>Therefore, the age criteria, and the application of the age criteria to the recipient as well as the donor in the case of donated eggs, rely in part on the Principle of Appropriateness.</p>
<b>4</b>	<b>Effective Healthcare</b>
<b>4.1</b>	<p>The CCG recognises in general terms that IVF, IUI, ICSI and sperm washing techniques can be effective in achieving their respective purposes in selected patient groups.</p>

<p><b>4.2</b></p> <p><b>4.2.1</b></p> <p><b>4.2.2</b></p> <p><b>4.2.3</b></p> <p><b>4.2.4</b></p>	<p>The CCG considers that some groups of patients are more likely to have successful outcomes than others. Therefore, the CCG sets the following policy criteria which rely on the Principle of Effectiveness:</p> <ul style="list-style-type: none"> <li>• The criteria relating to the age of the woman and of any egg donor (See also section 1.1;)</li> <li>• The criteria relating to the number of treatment units to which a patient is eligible (patients are most likely to succeed in their first attempt at IVF. Patients entering their second or subsequent treatment units are all ones who have failed in earlier treatment units and are less likely to be able to conceive through IVF);</li> <li>• The requirement to consider all previous treatment irrespective of the funding source of that treatment, when assessing the patient's eligibility to further treatment units;</li> <li>• The Body Mass Index Criteria, which is gender specific, and is based on evidence that this factor affects the success of IVF.</li> </ul>
<p><b>4.3</b></p>	<p>The distress caused by the failure to meet expectations when an offer of assisted conception funding is made in circumstances in which it is unlikely to succeed, also relates to the Principle of Effectiveness. The CCG considers that distress and anxiety caused by healthcare are dis-benefits that need to be taken into account when considering effectiveness, and this consideration therefore contributes to eligibility criteria including numbers of units.</p>
<p><b>5</b></p>	<p><b>Cost Effectiveness</b></p>
<p><b>5.1</b></p>	<p>The measure of cost effectiveness used by NICE and referenced in other CCG policies, is the quality adjusted life year (QALY). However, NICE acknowledges that it is likely that assisted conception is offered on the NHS for reasons other than QALY maximisation. For this reason few criteria in this policy rely solely on the Principle of Cost Effectiveness.</p>
<p><b>5.2</b></p>	<p>Uterine transplantation is a new technique for which some successes have been reported, but, it is too early to determine the overall success rate of the procedure, or to determine the rate of side effects and complications for the donor, the recipient and the baby. Therefore, the CCG considers that assisted conception is likely to be less cost effective when a transplanted uterus is used, than otherwise, and it seeks to make best use of the budget available for assisted conception services. Policy in relation to the use of a transplanted uterus is therefore based on the Principle of Cost-Effectiveness.</p>
<p><b>6</b></p>	<p><b>Ethics</b></p>
<p><b>6.1</b></p> <p><b>6.1.1</b></p>	<p>The CCG recognises possible ethical issues in relation to assisted conception, including issues in terms of:</p> <ul style="list-style-type: none"> <li>• the distress caused by the failure to meet expectations when an offer of assisted conception funding is made in circumstances in which it is</li> </ul>

6.1.2	<p>unlikely to succeed. The CCG expects all patients to give fully informed consent, but is still concerned that it does not wish to commission services that are likely to do more harm than good. This consideration therefore contributes to eligibility criteria (including numbers of units);</p> <ul style="list-style-type: none"> <li>the need to make sure that resources are distributed fairly and equitably, which is the reason why the policy includes eligibility criteria relating to cost effectiveness and to prioritising a suitable range of standard services.</li> </ul> <p>Eligibility criteria relating explicitly or implicitly to these issues therefore rely on the Principle of Ethics.</p>
6.2	<p>The CCG considers that it would be inequitable to enable certain patients to bypass certain eligibility criteria by taking an alternative pathway to that taken by the majority of assisted conception patients. For these reasons the following aspects of this policy rely on the Principle of Ethics:</p>
6.2.1	<ul style="list-style-type: none"> <li>the application of effectiveness criteria to all treatment modalities within the scope of this policy, and not only to the treatment modality to which the evidence base refers. (For example age criteria apply to all recipients of assisted conception services, and not only to women using their own eggs for the purposes of IVF);</li> </ul>
6.2.2	<ul style="list-style-type: none"> <li>an intention to carry out future treatment units differently is not a matter of exceptionality if a patient is requesting more treatment units than the usual entitlement.</li> </ul>
6.3	<p>The CCG is required to comply with legislation including the Human Fertilisation and Embryology (HFE) Act 2008 and the Equality Act 2010 and any primary or secondary legislation that amends or supersedes those Acts. The following aspects of this policy rely wholly or partly on those Acts:</p>
6.3.1	<ul style="list-style-type: none"> <li>sections relating to the duration of storage of gametes (HFE Act);</li> </ul>
6.3.2	<ul style="list-style-type: none"> <li>sections relating to the duration of storage of embryos (HFE Act);</li> </ul>
6.3.3	<ul style="list-style-type: none"> <li>sections relating generally to compliance with legislation.</li> </ul>
6.4	<p>The CCG recognises that surrogacy and gamete donation may give rise to a number of ethical and legal considerations. Those concerns are within the scope of the Principle of Ethics.</p>
7	<p><b>Affordability</b></p>
7.1	<p>The CCG has a limited budget and must make difficult choices. Many of the restrictions in this policy relate to one or more of the Principles of Appropriateness, Effectiveness, Cost-Effectiveness or Ethics. However, the need to manage resources within budget, and therefore the Principle of Affordability is also a basis for making restrictions to the commissioning of assisted conception services, and assisted conception services that are not normally commissioned in accordance with this policy are unlikely to accord with the Principle of Affordability (as well as possibly failing to accord with</p>

	other Principles).
<b>7.2</b>	For reasons of affordability, the CCG cannot offer unlimited treatments, for example in terms of the number of treatment units or the duration of storage of gametes or embryos.
<b>8</b>	<b>Exceptions</b>
<b>8.1</b>	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
<b>8.2</b>	It is acknowledged that there are continual developments in the technology available to assist conception. However, an intention to carry out future treatment units differently does not amount to exceptionality if a patient is requesting treatment units beyond the number normally offered in accordance with this policy.
<b>8.3</b>	Claims that assisted conception has been delayed beyond the upper age limit, for example because of hospital delays, waiting lists or the requirement to undergo medical treatment, do not amount to exceptionality. The CCG considers that it is irrational to set an age limit which is based on the chance of success (effectiveness), but to make exceptions to it when the reason for exceptionality does not mean that the chance of success is higher in the exceptional patient than in other patients to whom the criterion applies. However, a delay as a result of a hospital failure may need to be rectified by the hospital.
<b>8.4</b>	Claims related to the age or level of contact between a patient/s and a living child do not amount to exceptionality.
<b>8.5</b>	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
<b>9</b>	<b>Force</b>
<b>9.1</b>	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
<b>9.2</b>	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:
<b>9.2.1</b>	<ul style="list-style-type: none"> <li>• If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory;</li> </ul>
<b>9.2.2</b>	<ul style="list-style-type: none"> <li>• If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and</li> </ul>

	any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.
<b>10</b>	<p><b>References</b></p> <p>Equality Act (2010), Information and guidance on the Equality Act 2010, including age discrimination and public sector Equality Duty (<a href="https://www.gov.uk/guidance/equality-act-2010-guidance">https://www.gov.uk/guidance/equality-act-2010-guidance</a>)</p> <p>Fertility Fairness, Infographic and Information for Commissioners (<a href="http://www.fertilityfairness.co.uk/for-commissioners/">http://www.fertilityfairness.co.uk/for-commissioners/</a>)</p> <p>Human Embryo and Fertilisation Authority, UK Government's independent regulator overseeing fertility treatment and research. Provision of clear and impartial information to all affected by fertility treatment. (<a href="https://www.hfea.gov.uk/">https://www.hfea.gov.uk/</a>)</p> <p>Human Fertilisation and Embryology (HFE) Act 2008 (<a href="http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf">http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf</a>)</p> <p>NICE Clinical Guideline. (2013), Fertility: assessment and treatment for people with fertility problems. Published by the Royal College of Obstetricians and Gynaecologists. February 2013 (<a href="https://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3">https://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3</a>)</p> <p>NICE Clinical Guideline CG156 (2013 updated August 2016) Fertility Problems: Assessment and Treatment. National Institute for health and care excellence (<a href="https://www.nice.org.uk/guidance/CG156">https://www.nice.org.uk/guidance/CG156</a>)</p>

Date of adoption: 01.11.2018  
Date for review: 01.11.2021

## Appendix 1: Definitions and abbreviations

Anti-Müllerian Hormone (AMH)	A substance produced by small developing follicles, which is therefore an indicator of the number of follicles that start to develop at the beginning of each menstrual cycle. In women with a good ovarian reserve a large number of follicles start to develop and therefore the level is high. The converse is true. A low AMH level is an indicator of a high risk of a personal early menopause. A low AMH also indicates that IVF is less likely to succeed as it is more difficult to stimulate the ovaries.
Assisted Conception	A group of clinical processes intended to achieve a pregnancy, involving the temporary removal of gametes (eggs and / or sperm) from the human body. Assisted conception includes IUI and IVF.

Biological child	For the purposes of this policy, a biological child of an individual is either a genetic child of that individual (see separate definition), or a child that was conceived as part of a relationship including that individual, but with the use of a donated gamete instead of the gamete of that individual. Care needs to be taken to interpret the definitions of a biological child and a genetic child correctly.
Conception	The start of a pregnancy.
Embryo	A new organism in the earliest stage of development. In humans this is defined as the developing organism from the fourth day after fertilisation to the end of the eighth week
Embryo Transfer	See transfer.
Female Partner	Any reference to a female partner/ could relate to any of the following: <ul style="list-style-type: none"> <li>• The female partner in a heterosexual relationship</li> <li>• The partner in a female same sex relationship wishing to undergo assisted conception treatment with the intention of becoming pregnant.</li> <li>• A single female</li> <li>• A female to male transgender patient, who has retained female reproductive organs and wishes to undergo assisted conception treatment with the intention of becoming pregnant.</li> </ul>
Fertilise/ Fertilisation	The entry of a sperm into an egg to produce an embryo. (See separate definition for fertility and its derivatives).
Fertility	Technically fertility is a history of having produced children and fecundity is the (current) ability to produce children. However, the terms often have different meanings in common usage and for the purposes of this document fertility is used to mean the ability to produce children, and the word fecundity is not used. Derivatives including fertile, infertility and infertile accord with this definition. However, fertilise and fertilisation are defined separately.
Gametes	Eggs and / or sperm. Such cells contain half of the genetic material of the person who produced it and they can combine with gametes from the opposite gender to conceive a genetic child of that person.
Genetic Child	For the purposes of this policy, a genetic child of an individual is a child that was conceived using the gametes (eggs or sperm) of that individual. Such a child has half of the genetic material of that individual (and half from its other parent). Care needs to be taken to interpret the definitions of a biological child and a genetic child correctly.
Gonads	The sex glands. The gonads are the ovaries in the female, that produce eggs (ova) and the testicles in the male that produce sperm (spermatozoa). Both also produce sex hormones.
In vitro Fertilisation (IVF)	A type of assisted conception which includes medical stimulation of the ovaries to develop follicles and to induce ovulation; surgical harvesting of those eggs; harvesting of semen; using those eggs and that semen to achieve fertilisation in a laboratory setting; and transferring of a resulting embryo or embryos to the uterus. An extension of the process may include the frozen storage and transfer of surplus embryos.
Intra-cytoplasmic sperm injection (ICSI)	A type of in vitro fertilisation in which fertilisation is achieved by injecting sperm into the cytoplasm of the egg, rather than simply mixing the egg with the sperm. Sometimes abbreviated to ICSI. This is often used for male factor infertility. Within this policy, unless indicated otherwise, ICSI is regarded as a type of IVF, and the term IVF should therefore be regarded as including ICSI.
Intra-uterine Insemination (IUI)	A type of assisted conception preferred for some types of infertility, whereby semen is obtained from the male partner / donor and clinically inserted into the uterus of the female partner. Medication may be used for ovarian stimulation, but eggs are not removed from the body of the female partner. A similar process is intra vaginal insemination, in which the semen is inserted in the vagina. For the purpose of this policy, the term intra-uterine insemination also includes intra-vaginal insemination and the two processes are regarded as equivalent. Sometimes abbreviated to IU.
Menstrual Cycle	A physiological process in a woman, whereby an egg develops and is released from the ovary, and the uterus is prepared for the implantation of any embryo produced by the fertilisation of that egg. The term menstrual cycle should not be confused with the term Treatment Cycle.
Natural	Achievement of a pregnancy without the temporary removal of gametes (eggs and / or

Conception	sperm) from the human body.
Ovarian Reserve	A measure of the number of Oocytes (potential eggs) remaining in the ovary. The number declines with age, and by the time of the menopause no oocytes remain. An adequate ovarian reserve is defined by NICE CG156 para 1.3.3.2 as: a total antral follicle count of more than 4, OR an anti-müllerian hormone level of more than 5.4 pmol/l, OR a (day 3) follicle-stimulating hormone level of less than 8.9 IU/l
Patient	See female partner above.
Pre-implantation genetic diagnosis (PIGD)	A clinical process using IVF technology whereby embryos are created, but before transfer to the uterus they are checked to ensure that they do not have a particular genetic condition present in (or carried by) the parents. Only embryos without that condition are transferred. Sometimes abbreviated to PIGD.
Programme of IVF treatment	A Programme of IVF treatment is defined and described as part of the definition of a treatment unit.
Single	For the purposes of this policy a single person is regarded as a person who is not in a current relationship with a partner. It does not relate to the marital status of that person. A person may be single, or may not be single in accordance with this definition, irrespective of their marital status.
Surgical Fertility Services	Surgical procedures designed to correct a structural abnormality that is preventing pregnancy. The definition includes only the specific list of services defined in the scope of this policy (paragraph 2.3).
Transfer	When an embryo is produced as part of an IVF treatment unit it is then placed in the woman's uterus at the appropriate point in the menstrual unit in the hope that it will implant and a pregnancy will result. The terminology used is that the embryo is transferred to the uterus. A transfer usually places one embryo, but for the purpose of this policy the simultaneous placement of two or more embryos into the uterus is regarded as one transfer.

## Appendix 2: Associated OPCS

The codes applicable to this policy are:

OPCS codes
Q131, Q132, Q133, Q134, Q135, Q136, Q137, Q138, Q139, Q218, Q219, Y961, Y962, Y963, Y964, Y965, Y966, Y968, Y969.