

Document Control

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Placename CCG**Policies for the Commissioning of Healthcare****Policy for *Assisted Conception#* Services and *Surgical Fertility services#***

1	Introduction	The notes in this column are for information and are not part of the policy
1.1	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.	
1.2	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	Scope and definitions	
2.1	<i>Assisted conception#</i> is a group of clinical processes intended to achieve a healthy pregnancy, and involving the temporary removal of <i>gametes#</i> (eggs and / or sperm) from the human body.	

2.2	<p>The scope of this policy includes requests for:</p> <ul style="list-style-type: none"> • <i>in vitro fertilisation# (IVF#)</i>; • <i>in vitro fertilisation# (IVF#)</i> using <i>intra-cytoplasmic sperm injection# (ICS#)</i> technology; • <i>in vitro fertilisation# (IVF#)</i> using techniques to prevent the transfer of infectious diseases; • <i>intra-uterine insemination# (IUI#)</i>; • storage of <i>gametes#</i>; • the use of stored <i>gametes#</i>; • storage of embryos; • <i>transfer#</i> of stored embryos to the uterus; • services in preparation for <i>assisted conception#</i> ; • <i>assisted conception#</i> involving third parties (donors or surrogates) 	
2.3	<p>The scope of this policy also includes requests for the following <i>surgical fertility services#</i> :</p> <ul style="list-style-type: none"> • procedures to restore the patency of blocked fallopian tubes; • procedures to restore the patency of a blocked vas deferens; • uterine transplantation. <p>The scope therefore includes requests for funding for reversal of a surgical sterilisation.</p>	
2.4	<p>The scope of this policy does not include requests for:</p> <ul style="list-style-type: none"> • investigations to ascertain the cause of <i>infertility#</i>; • endometrial ablation; • the prescribing or administration of medicines to improve <i>fertility#</i> by increasing the probability of <i>natural conception#</i>; • <i>pre-implantation genetic diagnosis#</i> (except that a policy for <i>PIGD#</i> may make reference to aspects of this policy); • services to address recurrent miscarriage. 	

2.5	<p>The CCG recognises that a <i>patient#</i> may have certain features, such as</p> <ul style="list-style-type: none"> • no children; • difficulty in conceiving; • a diagnosis that implies that it may be difficult to conceive; • a risk of becoming unable to conceive in future; • <i>gametes#</i> or embryos in storage; • a blood-borne or sexually transmissible infection; • previous failed attempts at <i>assisted conception#</i> (including attempts that resulted in a conclusion that future attempts would be done differently); • a wish to use services within the scope of this policy. <p>Such features place the <i>patient#</i> within the group to whom this policy applies and do not make them exceptions to it.</p>	
2.6	<p>This policy addresses the circumstances of a transgendered person who wishes to have <i>gametes#</i> stored prior to surgical gender reassignment. Otherwise a transgendered person will be regarded as a person of their chosen gender and this policy will be applied in that context. Transgendered status per se is not a matter for exceptionality. However appendix 2 may be relevant to such individuals.</p>	
2.7	<p>Appendix 1 defines, describes and explains certain terms and abbreviations that are used in this policy and in its appendices. Those definitions are used for the purpose of the policy even if they differ from the way in which the terms are sometimes used in common or technical usage. When defined terms are used, they are indicated by coloured font and a hash (e.g. <i>conception#</i>).</p>	
3	<p>The Principle of Appropriate Healthcare</p>	
3.1	<p>The purpose of <i>assisted conception#</i> services is to enable people who are otherwise clinically unable to do so, to achieve a pregnancy leading to the birth of a healthy child. The CCG considers that <i>assisted conception#</i> to</p>	

	achieve this purpose may 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). However, the scope of this policy is limited to the commissioning of <i>assisted conception#</i> services for people with <i>clinical infertility#</i> .	
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 <i>assisted conception#</i> services and sets the following policy criteria which rely on the Principle of Appropriateness:</p> <ul style="list-style-type: none"> • the criteria requiring a health problem to be demonstrated, thus confirming that <i>conception#</i> cannot occur without an <i>assisted conception#</i> intervention. (see definition of <i>clinical infertility#</i>); • the criteria relating to previous children (see definition of <i>Eligible family structure#</i>). • 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. 	
3.4	Most requests for consideration under this policy will be from heterosexual couples who request <i>assisted conception#</i> services using their own <i>gametes#</i> to conceive a pregnancy in the female <i>partner#</i> . 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 <i>assisted conception#</i> would need to involve a third party. Decisions in such cases may 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. The basis for making such decisions is described in Appendix 2, which is part of this policy.	

3.5	<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 <i>clinical infertility</i># who request assisted conception services. The CCG considers it appropriate to focus its resources on that range of services. Therefore policy positions that the CCG will not normally commission services of an unusual, innovative or highly specialised nature, rely partly or wholly on the Principle of Appropriateness. That relates for example to 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>	<p>We do get a lot of IFR requests to go outside of the service agreements for services that in any case have a complex relationship with the eligibility criteria. Clarity is needed about whether we will look beyond the portfolio for patients# who otherwise satisfy the policy. This paragraph takes the hard line, but is subject to debate and consultation.</p>
3.6	<p>The CCG intends that the benefit of <i>assisted conception</i># to the <i>patient</i># is from acquiring parental status in respect of a child to whom the <i>patient</i># 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 <i>patient</i># (either or both partners) to make a contribution to the child's genome, then <i>assisted conception</i># to create an embryo entirely from third party <i>gametes</i># is not appropriate. Some <i>patients</i># in this situation may seek adoption or fostering. <i>Assisted conception</i># 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>	
3.7	<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. 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 to some extent on the Principle of Appropriateness.</p>	

4	The Principle of Effective Healthcare	
4.1	The CCG recognises in general terms that <i>IVF#</i> , <i>IUI#</i> , <i>ICS#</i> and sperm washing techniques can be effective in achieving their respective purposes in selected <i>patient#</i> groups.	
4.2	<p>The CCG considers that some groups of <i>patients#</i> 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"> • the criteria relating to the age of the woman and of any egg donor (Appendix 3 shows data demonstrating the decline in effectiveness after age 35. Appendix 6 demonstrates the higher risks associated with pregnancy in older women); • the criteria relating to the number of <i>treatment units#</i> to which a <i>patient#</i> is eligible (<i>patients#</i> are most likely to succeed in their first attempt at <i>IVF#</i>. <i>Patients#</i> entering their second or subsequent <i>treatment units#</i> are all ones who have failed in earlier <i>treatment units#</i> and are less likely to be able to conceive through <i>IVF#</i>.) • The requirement to consider all previous treatment irrespective of the funding source of that treatment, when assessing the <i>patient's#</i> eligibility to further <i>treatment units#</i>; • Criteria (which on some cases are gender specific) based on <ul style="list-style-type: none"> ➤ body mass index, ➤ alcohol consumption, ➤ caffeine consumption, ➤ tobacco use, and ➤ <i>ovarian reserve#</i> <p>which are all based on evidence that these factors affect the success of <i>IVF#</i> and have a biologically different impact on the success of assisted concept in the two genders.</p> 	<p>In terms of the age of the female partner# the CCG recognises that, while success rates decline with age, there is no objective cut-off point at which assisted conception# can be considered ineffective. Therefore the cut-off point applied in this policy is arbitrary. In setting the cut-off point used in this policy the CCG was mindful of current NICE guidance, but also of budgetary constraints, local views (both in preliminary opinion seeking among CCG stakeholders, and in formal consultation on this policy) of the need to distribute assisted conception# resources broadly, equitably and fairly, and of the desire to avoid subjecting patients# to healthcare that is unlikely to succeed.</p> <p>In terms of the funding source of previous treatment units#, the CCG is mindful that previous failure of <i>IVF#</i> is one of the strongest indicators of whether a further treatment unit# is likely to succeed. That indication is valid whatever the funding source of the treatment unit#.</p> <p>The CCG recognises the references in NICE guidance to body mass index, alcohol consumption, caffeine consumption and tobacco use.</p>
4.3	The distress caused by the failure to meet expectations when an offer of assisted concept 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 cycles.	
4.4	The criteria limiting surgical sperm retrieval to one attempt per person are based on the Principle of Effectiveness, with recognition that if one attempt has failed a subsequent attempt is unlikely to do so.	
5	The Principle of Cost Effectiveness	
5.1	The usual measure of cost effectiveness, used by NICE and referenced in other CCG policies, is the quality adjusted life year (QALY). However it is difficult or impossible to measure the success of <i>assisted conception#</i> services in terms of QALY. Hence this policy seeks to achieve best value for money within the scope of <i>assisted conception#</i> arena, but does not make direct comparison with the cost effectiveness of other services. For this reason few criteria in this policy rely directly on the Principle of Cost Effectiveness.	
5.2	<p>Uterine transplantation is a new technique for which successes have been reported. However it is too early to determine the overall success rate of the procedure, although it is reasonable to expect that it would be lower than in a non-transplanted uterus. It is also too early to determine the rate of side effects and complications for the donor, the recipient and the baby, although some adverse effects would be expected, and any adverse effect attributable to transplantation would not be a feature of <i>assisted conception#</i> without transplantation. Therefore the CCG considers that <i>assisted conception#</i> 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 concept services.</p> <p>Furthermore, if uterine transplantation was commissioned the CCG would</p>	<p>The first success from uterine transplantation is described in: "<i>Livebirth after uterus transplantation Brännström, Mats et al. The Lancet, Volume 385, Issue 9968, 607 – 616</i>"</p>

	<p>consider one transplant procedure to be equivalent to at least two <i>treatment units#</i> of <i>assisted conception#</i> treatment. That would fully utilise the <i>patient's#</i> entitlement under this policy. It would therefore be irrational for the CCG to commission uterine transplantation if (as would be expected) <i>IVF#</i> would then be required to achieve a pregnancy.</p> <p>Policy in relation to the use of a transplanted uterus is therefore based on the Principle of Cost-Effectiveness.</p>	
5.3	<p>In the case of a <i>patient#</i> with blocked tubes or another clinical condition that would be amenable either to surgery or to <i>assisted conception#</i> services, the CCG may consider the circumstances of the individual <i>patient#</i> and may apply the criterion of cost effectiveness in deciding which treatment strategy to adopt. As the CCG does not commission <i>assisted conception#</i> for <i>patients#</i> who already have children, the CCG may decide on grounds of equity to consider only the costs, benefits and probabilities of achieving a first pregnancy and may disregard any costs or benefits beyond the point of a first successful live birth.</p>	
6	The Principle of Ethics	
6.1	<p>The CCG recognises possible ethical issues in relation to <i>assisted conception#</i>, including issues in terms of:</p> <ul style="list-style-type: none"> • the distress caused by the failure to meet expectations when an offer of assisted concept funding is made in circumstances in which it is 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 cycles); • 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 	

	<p>standard services.</p> <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 <i>patients#</i> to bypass certain eligibility criteria by taking an alternative pathway to that taken by the majority of <i>assisted conception# patients#</i>. For these reasons the following aspects of this policy rely on the Principle of Ethics:</p> <ul style="list-style-type: none"> • 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 <i>assisted conception#</i> services, and not only to women using their own eggs for the purposes of <i>IVF#</i>); • the statements in section 9.3 that an intention to carry out future <i>treatment units#</i> differently is not a matter of exceptionality if a <i>patient#</i> is requesting more than <i>treatment units#</i> than the usual entitlement. • The recognition of a surgical attempt to restore <i>fertility#</i> as being equivalent to a <i>treatment unit#</i> of <i>IVF#</i>. • The requirement for couples to be in a relationship of at least two years duration (even if there is a clinical reason for their <i>infertility#</i>, thus achieving equity between <i>patients#</i> who have to demonstrate failure to conceive after 24 months of attempting, and <i>patients#</i> with a clinical diagnosis of <i>infertility#</i>) 	<p>It may be a matter for consultation and legal advice to consider whether the application of age criteria and some of the lifestyle criteria to the female partner# but not to the male partner discriminates against women.</p> <p>The duration of the relationship may be a matter for consultation / legal advice</p>
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> <ul style="list-style-type: none"> • sections relating to the duration of storage of <i>gametes#</i> (HFE Act); • sections relating to the duration of storage of embryos (HFE Act); • sections relating generally to compliance with legislation. 	
6.4	<p>The CCG recognises that surrogacy and <i>gamete#</i> donation may give rise to a</p>	

	number of ethical and legal considerations, including those set out at Appendix 2 to this policy” Those concerns are within the scope of the Principle of Ethics.	
7	The Principle of Affordability	
	The CCG can afford only a limited budget for <i>assisted conception#</i> services.	
8	Policy	
8.1	<p>The CCG may commission a first <i>treatment unit#</i> of <i>assisted conception#</i> services for a couple when all of the following criteria are satisfied at the date on which the <i>treatment unit#</i> commences:</p> <ol style="list-style-type: none"> a. <i>Clinical infertility#</i> has been demonstrated; b. The couple are in an <i>Eligible family structure#</i> in terms of previous children; c. Neither partner has previously had a <i>treatment unit#</i> or part of a <i>treatment unit#</i> of <i>assisted conception#</i> irrespective of the source of funding of that <i>treatment unit#</i>, unless it can be clearly demonstrated that that unit of treatment was in a different relationship and either the cause of the <i>infertility#</i> was attributable predominantly to the <i>other partner#</i> in that relationship or the treatment was not related to <i>clinical infertility#</i>; d. The female <i>partner#</i> has not yet reached the age of 43 years. 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 <i>infertility#</i>. e. At the commencement of the <i>treatment unit#</i>, the female <i>partner#</i> seeking to become pregnant has a body mass index in the range 19-30; f. The female <i>partner#</i> is a non-smoker, consumes no more than one unit of alcohol per day, and consumes no more than two caffeine containing drinks per day, and commits to remain so throughout the <i>treatment unit#</i> and until the completion of any resulting pregnancy; 	A consultation question is whether the criteria in items d-g should be applied to both partners, or just to the one for whom there is evidence of effectiveness.

	<ul style="list-style-type: none"> g. The other partner# is a non-smoker, consumes no more than one unit of alcohol per day, and commits to remain so throughout the <i>treatment unit</i>#; h. If the female <i>partner</i># is aged 40 or more, her <i>ovarian reserve</i># has been tested within the previous 12 months and found to be adequate (as defined in Appendix 1); i. Except when the purpose of the treatment unit is to transfer those embryos, the couple shall not have embryos in storage from a previous <i>treatment unit</i># (irrespective of the funding source of that unit), and shall not have permitted embryos from a previous <i>treatment unit</i># to be destroyed; j. The couple are in a relationship of at least two years duration. 	
	<ul style="list-style-type: none"> k. The couple are not genetically related to the extent of sharing a common grandparent, and they are not known to have, or to carry, a genetic condition that has a probability of 50% or more of affecting any child, and means that an affected child is unlikely to live until the age of one year. 	<p>Comments on this need to be invited in consultation</p>
<p>8.2</p>	<p>The CCG may commission a second <i>treatment unit</i># of <i>assisted conception</i># services for a couple when all of the following criteria are satisfied at the date on which the <i>treatment unit</i># commences:</p> <ul style="list-style-type: none"> a. <i>Clinical infertility</i># has been demonstrated; b. The couple are in an <i>Eligible family structure</i># in terms of previous children; c. Neither partner has previously had more than one <i>treatment unit</i># or part of a <i>treatment unit</i># of <i>assisted conception</i># irrespective of the source of funding of any <i>treatment unit</i>#, unless it can be clearly demonstrated that that unit of treatment was in a different relationship and either the cause of the <i>infertility</i># was attributable predominantly to the <i>other partner</i># in that relationship or the treatment was not related to <i>clinical infertility</i>#; d. The <i>female partner</i># has not yet reached the age of 40 years (43 years if the treatment unit amounts only to the transfer of stored embryos produced under a previous NHS funded treatment unit). Additionally, if 	<p>A consultation question is whether the criteria in items d-g should be applied to both partners, or just to the one for whom there is evidence of effectiveness.</p>

	<p>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 <i>infertility#</i>.</p> <ul style="list-style-type: none"> e. At the commencement of the <i>treatment unit#</i>, the <i>female partner#</i> seeking to become pregnant has a body mass index in the range 19-30; f. The <i>female partner#</i> is a non-smoker, consumes no more than one unit of alcohol per day, and consumes no more than two caffeine containing drinks per day, and commits to remain so throughout the <i>treatment unit#</i> and until the completion of any resulting pregnancy; g. The other partner<i>ner#</i> is a non-smoker, consumes no more than one unit of alcohol per day, and commits to remain so throughout the <i>treatment unit#</i>; h. (no criterion h for a second <i>treatment unit#</i>); i. Except when the purpose of the treatment unit is to transfer those embryos, the couple shall not have embryos in storage from a previous <i>treatment unit#</i> (irrespective of the funding source of that unit), and shall not have permitted embryos from a previous <i>treatment unit#</i> to be destroyed; j. The couple are in a relationship of at least two years duration. 	
	<ul style="list-style-type: none"> k. The couple are not genetically related to the extent of sharing a common grandparent, and they are not known to have, or to carry, a genetic condition that has a probability of 50% or more of affecting any child, and means that an affected child is unlikely to live until the age of one year. 	<p>Comments on this need to be invited in consultation</p>
<p>8.3</p>	<p>Decisions about the commissioning of <i>assisted conception#</i> when a third party is biologically involved in the process will be made in accordance with Appendix 2</p>	
<p>8.4</p>	<p>The CCG may commission services (investigations and / or treatments) that have the primary purpose of preparing for <i>assisted conception#</i>, only if the <i>patient#</i> is likely to satisfy the criteria in this policy for <i>assisted conception#</i> services in due course. A claim that the <i>patient#</i> plans to seek <i>assisted</i></p>	

	<i>conception#</i> services in the private sector will not normally be regarded as a matter for exceptionality in this respect.	
8.5	The CCG may commission a single attempt at surgical sperm retrieval (with cryopreservation if necessary) prior to ICSI in obstructive azoospermia or ejaculatory failure if all other attempts to correct these problems have failed, or in Klinefelter's syndrome patients before the age of 20. In the case of Klinefelter's syndrome, frozen storage will be offered in accordance with the criteria elsewhere in this policy; otherwise the expectation is that the retrieval attempt will be part of a current IVF / ICSI package, and frozen storage will be offered only until that package is complete, in the expectation that the package will take no more than 12 months. The CCG will apply a lifetime limit of one attempt at surgical sperm retrieval per person, irrespective of the source of funding for that attempt.	
8.6	Decisions about the commissioning of storage and subsequent use of <i>gametes#</i> and embryos are considered in Appendix 4. That appendix also considers the harvesting of <i>gametes#</i> for the purposes of storage. When there is an option, any offer of funding will normally be for storage in the form of <i>unfertilised# gametes#</i> .	
8.7	The CCG will not normally commission <i>assisted conception#</i> services using surrogacy. The reasons for this, and the consideration that the CCG will give to applications for exceptionality to this element of the policy, are described in paragraphs 3.5 and 6.4 above, in Appendix 2 and also in section 3 of Appendix 5.	
8.8	The CCG may commission services within the scope of this policy for <i>patients#</i> of either gender who have previously been sterilised only when all of the following criteria apply: <ul style="list-style-type: none"> • the only <i>biological child#</i> of the sterilised person has died; • that death had not occurred, and could not have reasonably been anticipated, at the time of the sterilisation; • the <i>patient#</i> is currently in a relationship and the couple otherwise 	

	satisfy the criteria for <i>assisted conception#</i> services.	
8.9	In cases in which either <i>assisted conception#</i> services or <i>surgical fertility services#</i> would represent a reasonable treatment option, then the CCG may take account of the probability of achieving one successful pregnancy, as well as the cost and the risk of side effects of each option in deciding which procedure to fund. The CCG may also take account of <i>patient#</i> preference.	
8.10	The CCG will not normally commission uterine transplantation, and neither will it normally commission <i>assisted conception#</i> services when the intention is that the pregnancy will be carried in a transplanted uterus.	
8.11	When <i>assisted conception#</i> 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 <i>partner#</i> and the <i>other partner#</i> who seek to benefit from the service. This also applies when the process involves surrogacy or <i>gamete#</i> donation. This is explained more fully in appendix 5 which is part of this policy.	
8.12	Except where indicated otherwise in this policy, <ul style="list-style-type: none"> the CCG expects to commission <i>assisted conception#</i> services in accordance with NICE technology appraisal guidance or NICE clinical guidance that may be in force at the time, and the CCG expects its service providers to deliver <i>assisted conception#</i> services in accordance with NICE technology appraisal guidance or NICE clinical guidance that may be in force at the time. 	
8.13	The CCG may commission services that fall within the scope of this policy only when they are offered by service providers within its portfolio of service agreements.	Legal advice is required. A number of IFR request are for infrequently requested services that are offered only in the private sector. It is perhaps rational to focus the limited budget on the mainstream services which can be commissioned most effectively and

		economically within service agreements with quality assurances.
8.14	In all respects this CCG will comply with legal requirements which will take precedence over other provisions of this policy.	
9	Exceptions	
9.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.	
9.2	A <i>patient</i> # may claim exceptionality on the basis that, as a result of a hospital delay or a health problem, treatment had not been possible before the upper age of eligibility had been passed. If such a claim is substantiated, the CCG may take a compassionate approach and may extend the age limit by up to 12 months for that particular <i>patient</i> #. An extension of more than 12 months would be irrational on the basis of the reducing probability of success and will not normally be offered.	A consultation question might ask whether this is reasonable. Perhaps we should take a strict view that as the policy is based on effectiveness, there will be no extension unless there is reason to believe that effectiveness is not an issue.
9.3	<p>There are continual developments in the technology available to assist <i>conception</i># . In a particular case, each piece of definition to patients treatment can be regarded to some extent as an experiment, with other possible approaches being tried if that piece of treatment fails. The amount of treatment for which a <i>patient</i># is entitled to NHS treatment is set in recognition of this. Therefore a case</p> <ul style="list-style-type: none"> • that new techniques have become available since a particular <i>patient</i># received treatment, such that the <i>patient</i># is likely now to be treated differently, or • that learning from that <i>patient's</i># previous <i>treatment unit</i># would lead to a different approach being taken in another <i>treatment unit</i># <p>does not amount to exceptionality if a <i>patient</i># is requesting <i>treatment units</i># of treatment beyond the number normally offered in accordance with this policy.</p>	

9.4	Some of the provisions of this policy may be relevant only when exceptionality has been demonstrated to other aspects of the policy.	E.g. provisions relating to surrogacy
10	Force	
10.1	This policy remains in force for a period of three years from the date of its adoption, or until it is superseded by a revised policy, whichever is sooner.	

Date of adoption

Date for review

DRAFT

APPENDIX 1

Definitions and abbreviations

AMH#	see <i>anti-müllerian hormone#</i>	
PGD#	See <i>pre-implantation genetic diagnosis#</i>	
Anti-Müllerian Hormone#	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 <i>menstrual cycle#</i> . In women with a good <i>ovarian reserve#</i> a large number of follicles start to develop and therefore the level is high. The converse is true. A low <i>AMH#</i> level is an indicator of a high risk of a personal early menopause. A low <i>AMH#</i> also indicates that <i>IVF#</i> 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 <i>gametes#</i> (eggs and / or sperm) from the human body. <i>Assisted conception#</i> includes <i>IU#</i> and <i>IVF#</i>	
Biological child#	For the purposes of this policy, a biological <i>child#</i> of an individual is either a genetic <i>child#</i> 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 <i>gamete#</i> instead of the <i>gamete#</i> of that individual. Care needs to be taken to interpret the definitions of a biological <i>child#</i> and a genetic <i>child#</i> correctly.	This definition is included for the purposes of equity. It means that means that if a couple in whom one partner cannot produce suitable <i>gametes#</i> to fertilise# the <i>gametes#</i> of the other partner#, successfully conceive using donated <i>gametes#</i> (clinically or otherwise), then for the purpose of this policy the resulting child will be regarded as the child of both partners and it will not be valid for the partner who did not contribute the <i>gamete#</i> to claim that they remain childless and in an Eligible family structure#.
Clinical Infertility#	<p>A state in which "<i>natural conception#</i>" is considered not to be possible. That may be established by a clinical diagnosis in which the organs required for the process (ovaries, fallopian tubes, testes etc.) are demonstrated not to be functioning on a complete and irreversible basis. It may also be established by a failure to conceive after attempting to do so by frequent heterosexual intercourse for a reasonable period of time.</p> <p>It should be noted that diagnoses such as endometriosis, polycystic ovarian syndrome, oligospermia, low <i>ovarian reserve#</i> etc., which are not absolute, do not by themselves amount to <i>clinical infertility#</i> . People with a condition such as these will not be regarded as having <i>clinical infertility#</i> unless they have demonstrated a failure to conceive in accordance with the paragraph above.</p> <p>It should be noted that frequent sexual intercourse normally means that it is timed to coincide with ovulation in every <i>menstrual cycle#</i>. If not timed, then the frequency</p>	<p>Karen Slade's definition: The CCG defines <i>infertility#</i> as the inability to conceive in a situation where <i>conception#</i> would normally be biologically plausible. The CCG categorises two types of <i>infertility#</i>: Explained infertility# – the inability to conceive due to a structural or functional abnormality in a situation where <i>conception#</i> would normally be biologically plausible. Explained <i>infertility#</i> may be caused by:</p> <ul style="list-style-type: none"> • Ovulatory disorders • Tubal damage • Factors in the male causing <i>infertility#</i> • Uterine or peritoneal disorders • Previous Sterilisation • Chemotherapy/Medication • Inability to have vaginal intercourse (e.g. physical disability, psychosexual problems, known risk of viral transmission) <p>Unexplained infertility# - the inability to conceive in the absence of any other known cause or modifiable risk factor for <i>infertility#</i> (specifically: smoking in either partner; a body mass</p>


	<p>needs to be such that the interval is less than the time of sperm viability, which may typically be around five days.</p> <p>It should be noted that self-insemination will not normally be accepted as an alternative to sexual intercourse as there is no assurance that an adequate technique has been used.</p> <p>It should be noted that a reasonable time for the demonstration of <i>clinical infertility</i># by frequent sexual intercourse for the purposes of this policy is normally two years.</p> <p>It should be noted that the demonstration of <i>clinical infertility</i># by frequent heterosexual intercourse for a reasonable period of time normally requires that sexual intercourse to be with the current partner, recognising that <i>clinical infertility</i># confirmed in this way may be due to a combination of factors from both partners.</p> <p>A circumstance (usually due to a communicable disease) in which one partner has clinical advice that unprotected sexual intercourse would be hazardous to the health of a sexual partner or to a child that may be conceived, may be regarded as equivalent to <i>clinical infertility</i>#, provided that the condition leading to that advice is permanent and irreversible, and also provided that <i>assisted conception</i># techniques would remove that risk.</p> <p>Circumstances described in the section of Appendix 2 titled "Two gender couples in a relationship that does not include sexual intercourse" may also be regarded as equivalent to <i>clinical infertility</i># .</p>	<p>index of 30 or over in either partner; a body mass index of less than 19 in the female partner#; excessive alcohol intake in the male partner) if:</p> <ul style="list-style-type: none"> • A woman of reproductive age has had regular unprotected vaginal intercourse for an average period of two years (NB. The exact period of expectant management may vary depending on the age of the patient#, i.e. a longer period for younger women and a shorter period for older women) <p>OR</p> <ul style="list-style-type: none"> • A woman of reproductive age has had 12 episodes of artificial insemination (IUI#) treatment (with either partner or donor sperm). <hr/> <p>Should failure of self insemination be counted as equivalent to failure to conceive?</p> <p>-----</p> <p>In the preliminary survey, 70% of responders would not regard self-insemination as suitable for demonstration of infertility#, even if the semen was donated from the same male of proven fertility#.</p> <p>In the preliminary survey, 69% of responders considered 2 years to be an adequate period of time, but only 15% considered one year to be an adequate period of time.</p> <p>In the preliminary survey, 96% of responders considered that fertility# could not be demonstrated by intercourse with a series of partners of unknown fertility#.</p>
Conception#	The start of a pregnancy.	

<p>Eligible Family Structure#</p>	<p>For the purposes of this policy, a couple will have an <i>Eligible family structure#</i> if: EITHER at least one partner is childless, having no living <i>biological child#</i> from this or any other relationship, irrespective of the level of contact with any such child; OR the only child of the couple has a diagnosed non-genetic terminal illness such that on the balance of probability that child is unlikely to live to age 18.</p> <p>That means that:</p> <ul style="list-style-type: none"> • a couple whose only child or children have died, MAY still be regarded as living in an <i>Eligible family structure#</i>; • a couple who have parental responsibilities for adopted or fostered children of whom they are not the biological parents MAY still be regarded as living in an Eligible family structure#; • a couple in which BOTH partners have a child or children from previous relationships will NOT be regarded as living in an <i>Eligible family structure#</i>, irrespective of the level of contact with any child or children; • a couple who have a biological <i>child#</i> or children will NOT be regarded as living in an <i>Eligible family structure#</i> irrespective unless their only child (or children) has a diagnosed non-genetic terminal illness such that on the balance of probability that child is unlikely to live to age 18. • a couple who have one or more <i>biological children</i> who have been adopted or fostered and therefore the couple no longer have parental responsibility for them, will NOT be regarded as living in an <i>Eligible family structure#</i>. 	<p>In the preliminary survey, only 15% of responders considered that funding should normally be offered to couples already have a child. Therefore this definition does not include such couples.</p> <p>In the preliminary survey, 56% of responders considered that funding should be offered in a scenario in which the only child has a terminal illness. Therefore this definition includes such couples if, on the balance of probability, the child in question is unlikely to live to age 18.</p> <p>In the preliminary survey, 63% of responders considered that funding should be offered if at least one partner is childless, thus not excluding a couple on the basis of one partner having a child from a previous relationship. Therefore this definition includes such couples.</p> <p>In the preliminary survey, responders considered a couple should not be excluded from funding simply on the basis of having an adopted child (63%) or a fostered child (89%) living with them. Therefore this definition includes such couples.</p> <p>In the preliminary survey, only 38% of responders considered that funding should normally be offered to couples whose only child(ren) has (have) non-genetic disabilities. Therefore this definition does not include such couples.</p> <p>If a couple have an only child who is unlikely to live to age 18 as a result of a non-genetic terminal illness, the CCG will not, on compassionate grounds, explore the question of whether either partner has a history of having children in previous relationships.</p> <p>It should be noted that this definition differs from the definitions in previous policies, which in many CCGs excluded couples on the basis of only ONE partner having previous children, or on the basis of having adopted children. These changes could have noticeable resource implications. Other differences (eg in relation to terminal illness) are unlikely to have resource implications.</p>
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Embryo Transfer#	See <i>transfer#</i>	
Fecundity#	See <i>fertility#</i> .	
Female Partner#	<p>In many cases in this policy the term <i>female partner#</i> is used in the assumption that the intention is for the same person to provide the egg, become pregnant, and take on the role and responsibility of mother of any child that may result from the requested treatment. Such a person is regarded as the female <i>partner#</i>. However there may be circumstances in which there is an intention for these functions to be delivered by different individuals. In such circumstances:</p> <ul style="list-style-type: none"> • if the term <i>female partner#</i> is clearly being used to refer to (or include) the egg donor, for example in a criterion relating to ovarian function or egg quality, then its use in that sense should be assumed. • if the term <i>female partner#</i> is clearly being used to refer to (or include) the person who is intended to be pregnant, for example in a criterion relating to health in pregnancy, then its use in that sense should be assumed; • otherwise the term <i>female partner#</i> applies to the person intending to take on the role and responsibility of mother. <p>In a circumstance in which the role of <i>female partner#</i> is shared between different individuals, the CCG may (on grounds of equity when compared with couples with only one person in that role, and in accordance with the Principle of Ethics) require both (or all) of those individuals to satisfy eligibility criteria.</p>	
Fertilise# / Fertilisation#	The entry of a sperm into an egg to produce an embryo. (See separate definition for <i>fertility#</i> and its derivatives).	
Fertility#	Technically <i>fertility#</i> is a history of having produced children and <i>fecundity#</i> is the (current) ability to produce children. However the terms often have different meanings in common usage and for the purposes of this document <i>fertility#</i> is used to mean the ability to produce children, and the word <i>fecundity#</i> is not used. Derivatives including <i>fertile#</i> , <i>infertility#</i> and <i>infertile</i> accord with this definition. However <i>fertilise#</i> and <i>fertilisation#</i> 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 <i>gametes#</i> from the opposite gender to conceive a genetic <i>child#</i> of that person.	
Genetic Child#	For the purposes of this policy, a genetic <i>child#</i> of an individual is a child that was conceived using the <i>gametes#</i> (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 <i>child#</i> and a genetic <i>child#</i> correctly.	
Genetic Illness#	For the purposes of this policy a genetic <i>illness#</i> is defined as one which relates to a coding anomaly at a location on the chromosome, and which after consideration of its	

	dominant or recessive nature, its location on the autosomal or sex chromosomes, and its penetrance, is considered to have a probability of at least 25% of being manifest in any <i>genetic child</i> # of a couple. The definition of a genetic <i>illness</i> # will also include one that is determined by an abnormality in the number of chromosomes, or by a chromosome translocation.	
ICSI#	See <i>intra-cytoplasmic sperm injection</i> #	
In vitro Fertilisation#	A type of <i>assisted conception</i> # 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 <i>fertilisation</i> # in a laboratory setting; and <i>transferring</i> # of a resulting embryo or embryos to the uterus. An extension of the process may include the frozen storage and <i>transfer</i> # of surplus embryos.	
Intra-cytoplasmic sperm injection#	A type of <i>in vitro fertilisation</i> # in which <i>fertilisation</i> # is achieved by injecting sperm into the cytoplasm of the egg, rather than simply mixing the egg with the sperm. Sometimes abbreviated to <i>ICSI</i> #. This is often used for male factor <i>infertility</i> #. Within this policy, unless indicated otherwise, <i>ICSI</i> # is regarded as a type of <i>IVF</i> #, and the term <i>IVF</i> # should therefore be regarded as including <i>ICSI</i> #.	
Intra-uterine Insemination#	A type of <i>assisted conception</i> # preferred for some types of <i>infertility</i> #, whereby semen is obtained from the male partner / donor and clinically inserted into the uterus of the female <i>partner</i> #. Medication may be used for ovarian stimulation, but eggs are not removed from the body of the female <i>partner</i> #. A similar process is intra vaginal insemination, in which the semen is inserted in the vagina. For the purpose of this policy, the term <i>intra-uterine insemination</i> # also includes intra-vaginal insemination and the two processes are regarded as equivalent. Sometimes abbreviated to <i>IUI</i> #.	
IUI#	See <i>intra-uterine insemination</i> #	
IVF#	See <i>in vitro fertilisation</i> #	
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 <i>fertilisation</i> # of that egg. The term <i>menstrual cycle</i> # should not be confused with the term Treatment Cycle	
Natural Conception#	Achievement of a pregnancy without the temporary removal of <i>gametes</i> # (eggs and / or sperm) from the human body.	
Other Partner#	A partner in a couple seeking <i>assisted conception</i> # who does not satisfy the definition of the female <i>partner</i> #. When the context is that the other <i>partner</i> # must be male, he may be referred to as the male partner, a term having the same meaning in this policy.	

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. A low <i>ovarian reserve</i> # can predict an early menopause and can also predict that fewer eggs will be produced in response to clinical ovarian stimulation. For the purposes of this policy, an adequate <i>ovarian reserve</i> # in a woman aged over 35, measured with the intention of identifying women with a higher chance of <i>IVF</i> # success, is defined (NICE CG165 para 1.3.3.2) as: a total antral follicle count of more than 4, OR an <i>anti-müllerian hormone</i> # level of more than 5.4 pmol/l, OR a (day 3) follicle-stimulating hormone level of at least 8.9 IU/l	
Patient#	The <i>patient</i> # in the context of this policy is defined as a couple comprising two people who are in a life-partnership relationship with each other.	The process of conceiving a child requires two people. This policy includes several eligibility criteria that can be met only by two people. Funding under this policy will be provided only to enable one couple of two people to have one child. It would be inequitable for the CCG to offer assisted conception# to <i>single</i> # people who are therefore not able to satisfy fully the eligibility criteria. It would be equally inequitable for two unassociated <i>single</i> # people to be able to have a child each, when a couple in a relationship are able to have one child between them. It is not affordable for the CCG to fund one child per person.
Pre-implantation genetic diagnosis#	A clinical process using <i>IVF</i> # technology whereby embryos are created, but before <i>transfer</i> # 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 <i>transferred</i> #. Sometimes abbreviated to <i>PIGD</i> #.	
Programme of IVF treatment#	A <i>Programme of IVF treatment</i> # is defined and described as part of the definition of a <i>treatment unit</i> #.	
Single	For the purposes of this policy a <i>single</i> # 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 <i>single</i> #, or may not be <i>single</i> # 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 <i>IVF</i> # <i>treatment unit</i> # it is then placed in the woman's uterus at the appropriate point in the <i>menstrual cycle</i> # in the hope that it will implant and a pregnancy will result. The terminology used is that the embryo is <i>transferred</i> # to the uterus. A <i>transfer</i> # usually places one embryo, but for the purpose of this policy the simultaneous placement of two or more embryos into the uerus is regarded as one <i>transfer</i> #.	

<p>Treatment Unit#</p>	<p>A <i>treatment unit#</i> is the currency used to describe the amount of <i>assisted conception#</i> treatment to which a <i>patient#</i> is eligible. One <i>treatment unit#</i> is defined as: EITHER Up to three separate attempts at <i>IUI#</i>, each in a different <i>menstrual cycle#</i>; OR One <i>Programme of IVF treatment#</i> comprising some or all of:</p> <ul style="list-style-type: none"> • ovarian stimulation • induction of ovulation • harvesting of eggs; • harvesting of semen; storage of eggs and/or semen in accordance with appendix 4 • <i>fertilisation#</i> of embryos, up to but not exceeding the maximum number that can be transferred fresh or after frozen storage, with reference to the remaining funding eligibility of the patient, and to NICE guidance in force at the time about embryo transfer strategies. • <i>transfer#</i> of one or more of those fresh embryos to the uterus; <p>OR Frozen storage of embryos in accordance with the provision of this policy and up to three separate attempts at <i>Embryo transfer#</i>, each in a different <i>menstrual cycle#</i>, using embryos produced in a previous <i>treatment unit#</i>, or using donated embryos. OR One surgical attempt to restore blocked fallopian tubes or vas deferens.</p> <p>Please note:</p> <ul style="list-style-type: none"> ❖ A <i>Programme of IVF treatment#</i> may be disregarded on one occasion only in the lifetime of a woman if it fails to reach the stage of an attempt to harvest eggs. Otherwise if a unit has been partially completed it will count as a whole unit for the purposes of calculating future eligibility for <i>assisted conception#</i> services. ❖ In <i>IVF#</i> treatment, the programme may amount to a single unit only if all of the embryos <i>fertilised#</i> and/or <i>transferred#</i> and/or stored are those produced by <i>fertilisation#</i> of eggs harvested in that same programme. ❖ if the number of embryos produced is more than can be <i>transferred#</i> in a single fresh <i>transfer#</i> attempt, then the storage and subsequent <i>transfer#</i> of surplus embryos will be regarded as a separate <i>treatment unit#</i> and funding will be provided only if the couple are eligible for a further unit. ❖ Some CCGs use the term Treatment Cycle in this context. However for this policy the term <i>treatment unit#</i> is preferred partly to avoid confusion with the <i>menstrual cycle#</i> and partly because the matter is not cyclical. ❖ An attempt at uterine transplantation, on the basis of its significant cost, would be regarded as equivalent to two units of treatment. 	
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	<p>❖ This definition does not exclude the possibility of eggs being harvested from a donor and (after <i>fertilisation#</i>) <i>transferred#</i> to the <i>patient#</i>, within a single <i>treatment unit#</i>.</p>	
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APPENDIX 2

The application of the Principle of Appropriateness in specifically defined circumstances.

Circumstances involving a third party

This appendix describes the criteria by which the CCG will make its decision when a request is received for funding for *assisted conception*# outside of a heterosexual relationship and/or biologically involving a third party.

In all circumstances described in this appendix, other aspects of the policy remain relevant. In particular:

- Paragraphs 3.2, 3.3 (first bullet point), 7.1 (first bullet point) and 7.2 (first bullet point) apply. Those paragraphs explain that the CCG will commission *assisted conception*# services only when *clinical infertility*# has been demonstrated, on the basis that the purpose of this policy is not to provide alternatives to natural conception when the obstacle to natural conception is outside of the health arena.
- The criteria for demonstrating *clinical infertility*# are the same as in any other circumstance and are as described Appendix 1 (under the definition of *clinical infertility*#).
- All other eligibility criteria in this policy need to be met.

In circumstances which biologically involve a third party, it is the responsibility of the *patient*# to find that third party, who shall not have *clinical infertility*#. The CCG will not offer funding for the process of finding third parties, and neither will it offer funding for the services of *gamete*# banks.

Circumstances in which *assisted conception*# funding requests may be received from outside of a heterosexual relationship and/or for services biologically involving a third party are as follows:

	Status of the female partner#	Status of the male partner	Policy	Notes
1	The female <i>partner</i> # has no <i>clinical infertility</i> #.	The male partner has no <i>clinical infertility</i> #.	No third party is required. The case is outside of the scope of this appendix.	

2	The female <i>partner#</i> has no <i>clinical infertility#</i> .	The male partner has limited <i>fertility#</i> , but has the potential to use his own sperm with <i>ICS#</i> .	No third party is required. The case is outside of the scope of this appendix.	
3	The female <i>partner#</i> has no <i>clinical infertility#</i> .	The male partner is completely and irreversibly unable to produce any sperm.	A sperm donor would be required to achieve pregnancy. The expectation is that the female <i>partner#</i> and the sperm donor are of normal <i>fertility#</i> , therefore there is no health problem that needs to be addressed to achieve <i>conception#</i> and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	Dissonant with table 9.1 row 2 of survey report, but accords with table 4.1 row 6.
4	The female <i>partner#</i> has <i>clinical infertility#</i> but has the potential to use her own eggs and uterus in <i>assisted conception#</i> .	The male partner has no <i>clinical infertility#</i> ..	No third party is required. The case is outside of the scope of this appendix.	
5	The female <i>partner#</i> has <i>clinical infertility#</i> but has the potential to use her own eggs and uterus in <i>assisted conception#</i> .	The male partner has limited <i>fertility#</i> , but has the potential to use his own sperm with <i>ICS#</i> .	No third party is required. The case is outside of the scope of this appendix.	
6	The female <i>partner#</i> has <i>clinical infertility#</i> but has the potential to use her own eggs and uterus in <i>assisted conception#</i> .	The male partner is completely and irreversibly unable to produce any sperm.	The CCG may offer funding for <i>IVF#</i> using donated sperm, provided that other eligibility criteria are met.	
7	The female <i>partner#</i> is completely and irreversibly unable to produce eggs; She has potential to use her own uterus.	The male partner has no <i>clinical infertility#</i> .	The CCG may offer funding for <i>IVF#</i> using donated eggs and male partner sperm.	

8	The female <i>partner#</i> is completely and irreversibly unable to produce eggs; She has potential to use her own uterus.	The male partner has limited <i>fertility#</i> , but has the potential to use his own sperm with <i>ICSI#</i> .	The CCG may offer funding for <i>ICSI#</i> using donated eggs and male partner sperm.	
9	The female <i>partner#</i> is completely and irreversibly unable to produce eggs; She has potential to use her own uterus.	The male partner is completely and irreversibly unable to produce any sperm.	The CCG may offer funding for the <i>transfer#</i> of a donated embryo. It is expected that the service provider will be able to identify such an embryo, with the consent of the <i>patients#</i> from whose <i>gametes#</i> it was produced, that would otherwise be destroyed. If no such embryo is available, then the CCG considers that it is not appropriate to fund the creation of an embryo when neither partner is making a genetic contribution, and therefore funding will not be offered.	
10	The female <i>partner#</i> is able to produce eggs but has no functioning uterus.	The male partner has no <i>clinical infertility#</i> .	The CCG may consider offering funding for <i>assisted conception#</i> using the eggs from the female <i>partner#</i> , the sperm from the male partner, and a surrogate to carry the pregnancy. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
11	The female <i>partner#</i> is able to produce eggs but has no functioning uterus.	The male partner has limited <i>fertility#</i> , but has the potential to use his own sperm with <i>ICSI#</i> .	The CCG may consider offering funding for <i>assisted conception#</i> including <i>ICSI#</i> using the eggs from the female <i>partner#</i> , the sperm from the male partner, and a surrogate to carry the pregnancy. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
12	The female <i>partner#</i> is able to produce eggs but has no functioning uterus.	The male partner is completely and irreversibly unable to produce any sperm.	The CCG may consider offering funding for <i>assisted conception#</i> using the eggs from the female <i>partner#</i> , the sperm from a donor, and a surrogate to carry the pregnancy. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
13	The female <i>partner#</i> is completely and irreversibly unable to produce eggs and has no functioning uterus.	The male partner has no <i>clinical infertility#</i> .	The expectation is that the male partner and the surrogate are of normal <i>fertility#</i> , therefore there is no health problem that needs to be addressed to achieve <i>conception#</i> and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	

14	The female <i>partner</i> # is completely and irreversibly unable to produce eggs and has no functioning uterus.	The male partner has limited <i>fertility</i> #, but has the potential to use his own sperm with <i>ICSI</i> #.	The CCG may consider offering funding for <i>assisted conception</i> # including <i>ICSI</i> # using the sperm from the male partner, and a surrogate / donor to provide eggs and to carry the pregnancy. The CCG takes no view about whether the surrogate and the egg donor is the same person. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
15	The female <i>partner</i> # is completely and irreversibly unable to produce eggs and has no functioning uterus.	The male partner is completely and irreversibly unable to produce any sperm.	Neither partner can participate biologically in the <i>conception</i> # or pregnancy. Theoretical options, including adoption or asking a fertile couple to have a child on their behalf, do not require healthcare interventions and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	
16	A <i>single</i> # person of either gender irrespective of <i>clinical infertility</i> # status, is seeking funding for <i>assisted conception</i> # using donor or surrogate assistance.		A <i>single</i> # person, irrespective of <i>clinical infertility</i> # status, does not satisfy the definition of a <i>patient</i> # in Appendix 1 of this policy and therefore will not normally receive funding for <i>assisted conception</i> # services.	
17	A female same gender couple in whom at least one partner does not have <i>clinical infertility</i> # .		A sperm donor would be required to achieve pregnancy. The expectation is that the female <i>partner</i> # and the sperm donor are of normal <i>fertility</i> #, therefore there is no health problem that needs to be addressed to achieve <i>conception</i> # and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	Dissonant with table 10.1 row 2 of survey report, but accords with table 4.1 row 6.
18	A female same gender couple in whom both partners have <i>clinical infertility</i> #, but at least one partner can produce eggs.		The CCG may consider funding for <i>assisted conception</i> # using the egg(s) of one of the partners and donor sperm. In the event of neither partner having a functioning uterus, then surrogacy may be considered. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
19	A female same gender couple in whom both partners have <i>clinical infertility</i> #, neither partner can produce eggs, but at least one partner has her own uterus.		The CCG may offer funding for the <i>transfer</i> # of a donated embryo. It is expected that the service provider will be able to identify such an embryo, with the consent of the <i>patients</i> # from whose <i>gametes</i> # it was produced, that would otherwise be destroyed. If no such embryo is available, then the CCG considers that it is not appropriate to fund the creation of an embryo when neither partner is making a genetic contribution, and therefore funding will not be offered.	

20	A female same gender couple in whom both partners are completely and irreversibly unable to produce eggs and neither has a functioning uterus.	Neither partner can participate biologically in the <i>conception#</i> or pregnancy. Theoretical options, including adoption or asking a fertile couple to have a child on their behalf, do not require healthcare interventions and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	
21	A male same gender couple in whom at least one partner does not have <i>clinical infertility#</i> .	A surrogate would be required to achieve pregnancy. The expectation is that the one partner in the couple, and the surrogate, are of normal <i>fertility#</i> , therefore there is no health problem that needs to be addressed to achieve <i>conception#</i> and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	
22	A male same gender couple in whom both partners have <i>clinical infertility#</i> , but clinical advice is that at last one partner would be suitable for <i>ICS#</i> .	The CCG may consider funding for <i>assisted conception#</i> using <i>ICS#</i> and a surrogate. Exceptionality to the CCG's position on surrogacy would need to be demonstrated.	
23	A male same gender couple in whom both partners have <i>clinical infertility#</i> , and clinical advice is that neither partner would be suitable for <i>ICS#</i> .	Neither partner can participate biologically in the <i>conception#</i> or pregnancy. Theoretical options, including adoption or asking a fertile couple to have a child on their behalf, do not require healthcare interventions and therefore the matter is outside of the scope of the CCG which will not normally offer funding.	

Surrogacy	
<p>The table above indicates that under some circumstances, surrogacy may be considered. However the CCG has concerns about surrogacy, as follows:</p> <ul style="list-style-type: none"> • NICE Clinical Guidance for the assessment and treatment of people with <i>fertility#</i> problems (CG 156, published February 2013) does not make reference to surrogacy. • NHS England's Interim Clinical Commissioning Policy (for Armed Forces Couples) does not make reference to surrogacy. • The Surrogacy Arrangement Act 1985 makes it an offence to "advertise" that "any person is or may be willing...to negotiate or facilitate the making of a surrogacy arrangement". An NHS Commissioner who "brokers" a surrogacy arrangement, or who is complicit in a surrogacy arrangements that is in breach of this legislation, may be committing an offence. 	<p>This paragraph, and especially the list of concerns, draws on advice apparently given by Hill Dickinson to Cheshire and Merseyside Fertility# Working Group (dated 2007). I received that advice under cover of an e-mail from Karen Slade (09 July 2014 16:27) We need to check with Hill Dickinson that they have no objection to the inclusion of this wording in the policy.</p>

- Legislation empowering the Secretary of State, acting through NSH bodies, to secure the effective provision of services for the prevention, diagnosis and treatment of illness does not appear to encompass treatment other than that provided directly to the person suffering from an illness or disability.
- The CCG would be promoting an action that could damage the health of a healthy person, for a benefit in another person which is not lifesaving.
- The CCG would not expect to be involved in the identification of the surrogate, either directly or through its service providers.
- The legal parentage of the child could be disputed unless and until a parental order has been granted.
- A parental order is possible only if parental responsibility is *transferred*# to a biological parent of the child (i.e. the couple on whose behalf the surrogate is carrying the pregnancy must have provided at least one of the *gametes*#).
- The surrogate may change her mind and have a termination
- The surrogate may refuse to give the child to the commissioning couple.
- The commissioning parents may change their mind and the surrogate may decline to care for the child resulting in an "unwanted baby". This may arise if antenatal screening tests detect genetic or congenital defects.
- The surrogate may become disabled (or die) as a result of complications of pregnancy. Issues may arise around compensation, around long term care for the surrogate, and around provision for dependants of the surrogate.
- There may be disputes about the surrogate mother's continuing involvement with the child.
- The surrogate or the child's biological siblings may experience ongoing emotional issues arising from the arrangement.
- All parties will require counselling before, during and after childbirth, which will be a significant additional cost in excess of the usual level of funding for *assisted conception*# services.
- Agreement the CCG responsible for funding the healthcare of the surrogate would need to be in place
- The CCG must comply with other legislation and guidance that may be in force at the time, including Human Fertilisation and Embryology guidance and legislation, and NICE guidance.
- The CCG considers that it is unethical for a surrogate to be paid (by the CCG or by the *patient*#) for her services.
- The legal costs incurred in making and assuring the CCG of provisions in these respects will be a

<p>significant additional cost in excess of the usual level of funding for <i>assisted conception#</i> services, and it may be outside of the remit of the CCG to fund the necessary legal work.</p> <ul style="list-style-type: none"> • The provisions of paragraph 3.5 of this policy. <p>Therefore CCG policy is that it will not normally commission surrogacy because it does not believe that patients would normally satisfy the CCG in these respects. However, it will consider a claim of exceptionality if a patient does make a case that would satisfy the criteria. While the CCG may not be directly responsible it does not wish to be involved in creating a situation in which there are physical risks for a surrogate, social risks for the baby, and the other risks stated pertain. Exceptionality to this aspect of the policy will require:</p> <ol style="list-style-type: none"> 1. The CCG to be satisfied (usually on the basis of legal advice) that robust arrangements are in place to address the above considerations. 2. Funding arrangements to be agreed with the surrogate's CCG in accordance with the provisions of section 3 of appendix 5 of this policy 	
<p><i>Gamete#</i> and Embryo Donation</p>	
<p>Many of the concerns listed above in relation to surrogacy, especially the concern about providing healthcare to a person who is not the patient, may also apply to <i>gamete#</i> or embryo donation. However they apply only to a lesser extent and this policy does not therefore exclude the use of donated <i>gametes#</i>, but the CCG may still seek to be assured that robust arrangements are in place to address all of the considerations listed in the surrogacy section above.</p>	
<p>The use of donated embryos that would otherwise be destroyed</p>	
<p>The provisions of this appendix may be waived when a <i>patient#</i> (or a <i>single#</i> person) who is otherwise eligible for <i>assisted conception#</i> services is willing to use (with due consent) a donated stored embryo that would otherwise be destroyed. In such a case funding may be offered for <i>transfer#</i> of such an embryo to the uterus, with two such <i>transfers#</i> being regarded as equivalent to one <i>treatment unit#</i>.</p>	
<p>Two gender couples in a relationship that does not include sexual intercourse</p>	
<p>The CCG recognises that sexual intercourse is the normal way of achieving a pregnancy, and that the purpose of <i>assisted conception#</i> services is not to provide an alternative means of <i>conception#</i> for a couple who are not having sexual intercourse. However the CCG may regard an inability to have sexual intercourse as being equivalent to <i>clinical infertility#</i>, and therefore may commission <i>IU#</i> under the following circumstances:</p>	

Circumstance 1:

- ❖ EITHER there is a structural abnormality of the genital organs such that sexual intercourse would be impossible, OR 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.
AND
- ❖ the gynaecologist responsible for delivering the *IU#* advises that the feature making sexual intercourse impossible would not mean that pregnancy or delivery would be clinically inadvisable, from the perspective either of the mother or of the child.

Circumstance 2:

- ❖ There is irreversible erectile dysfunction associated with a clinical condition reasonably assumed to be causal (e.g. diabetes, multiple sclerosis, spinal cord dysfunction), but sperm can nevertheless be obtained.

Circumstance 3: There is a serious psychosexual problem. Such a problem will normally satisfy most or all of the following criteria:

- ❖ The *patient#* has seen a senior clinical psychologist who supports the use of *IU#*;
- ❖ The psychosexual problem leads to a physical obstacle to sexual intercourse, e.g. erectile or ejaculatory failure or vaginismus;
- ❖ The senior clinical psychologist advises that the serious psychosexual problem is pathological;
- ❖ The senior clinical psychologist advises that the serious psychosexual problem cannot be reversed;
- ❖ The senior clinical psychologist advises that the serious psychosexual problem does not amount to a non-heterosexual gender preference (the provisions of this section are not intended to address the circumstances of people with a same sex gender preference which is not normally considered to be pathological).
- ❖ The senior clinical psychologist has considered the possibility of a history of sexual abuse or sexual assault as the cause of the problem and has undertaken appropriate management of that cause without benefit;
- ❖ The senior clinical psychologist confirms that the serious psychosexual problem is not simply a manifestation of a more general problem with the relationship;
- ❖ The senior clinical psychologist confirms that the serious psychosexual problem is not caused by a fear, dislike or concern about *conception#*, pregnancy, congenital anomaly or parenthood;
- ❖ Medications to address erectile dysfunction / anxiety etc., have been considered and either regarded as clinically inappropriate or have failed.

APPENDIX 3**Success rates for *IVF#* and *ICS#***

According to the Human Fertilisation and Embryology Authority (HFEA) (see <http://www.hfea.gov.uk/IVF-figures-2006.html>) the Overall success rate for *IVF*# in 2010 was 25.6%. That breaks down by age as:

- 32.2% for women aged under 35
- 27.7% for women aged between 35–37
- 20.8% for women aged between 38–39
- 13.6% for women aged between 40–42
- 5.0% for women aged between 43–44
- 1.9% for women aged 45 and over

Success rates for *IVF*# and *ICSI*# are very similar and the above results combine both techniques.

Those data do not indicate whether the successes were achieved in the first, second, third or subsequent *treatment unit*#. However there is also evidence that the success rate in a first *treatment unit*# is higher than the success rate in a second *treatment unit*#, which in turn is higher than the success rate in a third *treatment unit*# and so on. That is because the *patients*# who are most likely to have success from *IVF*# will not go on to have subsequent (NHS funded) *treatment units*#, and therefore the population of *patients*# who enter a second or subsequent *treatment unit*# will contain a higher proportion of *patients*# with more challenging *infertility*#.

It is difficult to find objective data on the relative success rate of first, second, third and subsequent treatment units#. However one source (<http://www.infertilityny.com/blog/how-many-times-do-i-need-to-try-IVF-before-it-works>) indicates that "about one third (33%) of patients# experience a live birth after their first *IVF*# treatment unit#. For women who go through three treatment units#, the success rate rises to around 70% of patients#." This is more optimistic than the HFEA data, and the data source is not quoted. However the estimate that about 33 out of every 70 women who will succeed after three treatment units#, will actually succeed in the first treatment unit#, seems reasonable.

A mathematical model that fits both the HFEA data and the above estimate is shown below. This model assumes that the population of treated women includes a percentage who have the potential to succeed and a percentage who do not have the potential to succeed. In each treatment unit#, 33.8% of those capable of success will actually succeed.

That model gives success rates by age and treatment unit# as follows:

Age	% capable of success	First unit	Second unit	Third unit
All ages	81.7%	27.6%	25.3%	22.4%
Under 35	100.0%	32.2%	32.2%	32.2%
35–37	86.6%	29.3%	27.4%	25.0%
38–39	69.6%	23.5%	20.4%	16.9%
40–42	49.0%	16.6%	13.1%	10.0%
43–44	20.0%	6.8%	4.8%	3.3%
45 and over	8.0%	2.7%	1.8%	1.2%

APPENDIX 4

**Issues relating to the storage and subsequent use of *gametes#* and embryos
(This appendix also considers the harvesting of *gametes#* for the purposes of storage)**

<p>Appendix 4, Part I - Storage of <i>gametes#</i> or embryos when a person is likely to lose the ability to produce <i>gametes#</i>, and is wishing to store them for use in a possible future relationship</p>		
<p>A4.1.1</p>	<p>A <i>patient#</i> may have condition that is either life threatening or otherwise overwhelming in its severity such that it needs to be treated immediately. That treatment will remove or irreversibly damage the gonads (ovaries or testicles). The expected damage may prevent the production of <i>gametes#</i>, or may result in the <i>gametes#</i> being so likely to carry genetic damage that there is clinical advice to the <i>patient#</i> that it would be unwise to attempt to conceive subsequently.</p> <p><i>Patients#</i> falling into this category include (but are not limited to)</p> <ul style="list-style-type: none"> • those who have a diagnosed malignant disease affecting the reproductive organs or surrounding structures; • those who (on the basis of genetic advice) are assessed as having more than a 10% probability of developing ovarian or testicular cancer during the period of <i>gamete#</i> storage as defined in paragraph A4.3.2 below. (It is expected that few <i>patients#</i>, even with known genetic mutations, will suffer this level of risk). <p>In such circumstances, it is considered that the <i>patient#</i> has no reasonable option of deferring the treatment until after they have achieved parenthood.</p> <p>The CCG may commission the harvesting and storage of <i>gametes#</i> from such <i>patients#</i>, provided that there is a reasonable expectation that they will satisfy the eligibility criteria for <i>assisted conception#</i> at the time when they wish to use those <i>gametes#</i>.</p>	<p><i>Consultation question. Is this a reasonable level of risk? (The lifetime risk of ovarian cancer is about 54% for BRCA1 carriers – King et al - Science 24 October 2003: Vol. 302 no. 5645 pp. 643-646</i></p>
<p>A4.1.2</p>	<p>A <i>patient#</i> may have a condition that does not fall into the category above</p>	

	<p>in terms of the urgent need for treatment, but treatment of that condition will similarly remove or irreversibly damage the gonads.</p> <p><i>Patients#</i> falling into this category include (but are not limited to)</p> <ul style="list-style-type: none"> • those seeking gender reassignment; • those with a level of genetic risk of ovarian or testicular cancer that is raised, but not to the extent that places them into the category defined in section A4.1.1. <p>The CCG will not normally commission the harvesting and storage of <i>gametes#</i> from people in this category, on grounds of appropriateness.</p>	<p>Karen Slade wording: The CCG considers that the cryopreservation of <i>gametes#</i> for <i>patients#</i> who are about to undergo gender reassignment is not appropriate for commissioning as the <i>patient#</i> is considered to be consenting to sterilisation as part of gender reassignment treatment. (NB legal advice would suggest not using the KS wording)</p>
<p>A4.1.3</p>	<p>A <i>patient#</i> may have a condition that carries a risk of premature failure of the gonads.</p> <p><i>Patients#</i> falling into this category include (but are not limited to) women who have been diagnosed as having a low <i>ovarian reserve#</i> and men with Klinefelter's syndrome.</p> <p>In general terms, if:</p> <ul style="list-style-type: none"> • there is a robustly determined probability of 50% or more that the gonads will fail completely within 12 months (or before the age of 22 in a <i>patient#</i> currently below the age of 21) AND • current gonadal function is currently normal, or sufficiently close to normal to expect the successful harvest of a good number of good quality <i>gametes#</i>, AND • there is a reasonable expectation that the <i>patient#</i> will satisfy the eligibility criteria for <i>assisted conception#</i> at the time when they wish to use those <i>gametes#</i>. <p>then the CCG may commission the harvesting and storage of <i>gametes#</i>.</p> <p>Specifically in relation to low <i>ovarian reserve#</i>, the CCG's position is as follows. Low <i>ovarian reserve#</i> carries a high risk of a premature menopause. Cases are detected by low <i>anti-müllerian hormone#</i> (<i>AMH#</i>)</p>	<p>The figures of 50%, 12 months and an age of 22 are arbitrary and need to be tested in consultation.</p>

	<p>levels or high Follicle Stimulating Hormone (FSH) levels). The use of AMH# testing is currently increasing, and it is not affordable for the CCG to commission embryo storage for patients# with low level results on this test. By way of example, it is a matter of definition that a tenth of the female population of a particular age will be found to be below the tenth centile if tested. Such women may worry about their fertility#, and may request gamete# storage, but most will continue for a considerable number of years before experiencing a menopause. However those whose level is so low that they are at a very high risk of complete and imminent ovarian failure will already have lost ovarian function such that attempts to harvest viable eggs are less likely to succeed. It is therefore expected that the point at which the second bullet point above ceases to be satisfied, will occur some considerable time before the first bullet point is satisfied. For this reason the CCG will not normally commission the harvesting and storage of eggs for this group of patients# in accordance with the Principle of Effectiveness.</p> <p>Specifically in relation to Klinefelter's syndrome, the CCG's position is as follows. Klinefelter's syndrome is a chromosomal anomaly that reduces male fertility#. Adolescents may have some ability to produce sperm, either in their ejaculate or by recovery from a testicular biopsy. That ability declines with age and also with testosterone replacement therapy. There is a theoretical risk of anomalies in the sex chromosomes being passed to the next generation but those risks are not proven in practice (cells with abnormal chromosome composition are the least likely to complete development into sperm) and the resultant offspring (with XXX or XXY chromosome compositions) would not (except for the features of Klinefelter's syndrome itself) have significant problems in terms of limited life expectancy or disability. Therefore the CCG may commission the harvesting and storage of sperm from patients# with Klinefelter's syndrome if they can be diagnosed and harvesting carried out before the age of 20, but not thereafter in accordance with the Principle of Effectiveness.</p>	<p>Ovarian failure and Klinefelter's syndrome are contrasting conditions in different genders and the suggested approach is different. There is an arbitrary element to both aspects of the policy and this needs to be tested in the consultation (to assure that we are applying the principle of effectiveness the same way in both genders).</p>
<p>Appendix 4, Part 2- Storage of gametes# or embryos when assisted conception#</p>		

procedures produce more <i>gametes#</i> or embryos than can be used immediately.		
A4.2.1	<p>Appendix 1 in its definition of a <i>treatment unit#</i>, determines the number of embryos that may be produced in a <i>treatment unit#</i> commissioned by this CCG. That is normally three embryos. One of those embryos may be <i>transferred#</i> fresh, and the other two may be <i>transferred#</i> in (separate) subsequent <i>transfer#</i> attempts. However in a woman aged 40-42, NICE guidance permits two embryos to be <i>transferred#</i> per attempt and therefore if that guidance is to be followed in a particular <i>patient#</i>, up to six embryos may be produced, in the expectant that up to a total of three <i>transfer#</i> attempts, each of two embryos, will be offered.</p> <p>If the number of embryos produced is more than can be <i>transferred#</i> in three attempts, the storage and use of embryos for a fourth and subsequent <i>transfer#</i> will be regarded as a separate <i>treatment unit#</i> and funding will be provided only if the couple are eligible for a further unit.</p>	
A4.2.2	<p>Funding may be provided for the storage of surplus <i>unfertilised#</i> eggs:</p> <ul style="list-style-type: none"> • if the number of eggs <i>fertilised#</i> is no more than the number that could be <i>transferred#</i> immediately in the fresh state, and • if the couple are eligible for a further <i>treatment unit#</i> of treatment, in which case storage of surplus eggs may be offered as an alternative to harvesting fresh eggs for that <i>treatment unit#</i>. 	
A4.2.3	The CCG will not normally provide funding for the storage of surplus sperm / semen except in accordance with section 1 of this appendix.	
Appendix 4, Part 3- Duration of Storage.		
A4.3.1	<p>Funding for storage of embryos will continue until one of the following occurs:</p> <ul style="list-style-type: none"> • The female <i>partner#</i> reaches the age of 43; • The embryo has been in storage for at least ten years; • The couple have had a live birth and now have a living child who 	

	<p>has reached the age of one year;</p> <ul style="list-style-type: none"> The female <i>partner</i># dies. <p>The CCG expects the service provider to give the <i>patient</i># at least six months' notice that NHS funding for the storage will cease, and this will be built into the service agreement.</p> <p>The CCG expects the Trust to give the <i>patients</i># the option of continuing to fund the storage beyond the point at which CCG funding ceases.</p>	
<p>A4.3.2</p>	<p>Funding for storage of <i>gametes</i># will continue until one of the following occurs:</p> <ul style="list-style-type: none"> The <i>patient</i># reaches the age of 43 years; The <i>gametes</i># have been in storage for at least ten years and the <i>patient</i># has reached the age of 35 years; The <i>patient</i># is the parent of a living child who has reached the age of one year; The <i>patient</i># dies. <p>The CCG expects the service provider to give the <i>patient</i># at least six months' notice that NHS funding for the storage will cease, and this will be built into the service agreement.</p> <p>The CCG expects the Trust to give the <i>patient</i># the option of continuing to fund the storage beyond the point at which CCG funding ceases.</p>	<p>The age of 43 in the first bullet point means that funding will not continue beyond the age at which a woman ceases to be eligible for other assisted conception# services.</p> <p>The age of 35 in the second bullet point recognises that in some cases gametes# may be stored at a very early age and an expectation that they will be used within ten years is unreasonable. Embryos are unlikely to be stored from a very young age and (and not before the patient# enters a partnership) therefore an equivalent age does not appear in relation to embryo storage.</p>
<p>APPENDIX 5</p>		
<p>The funding offer when some participants in <i>assisted conception</i># are the responsibility of other CCGs.</p>		

1. The CCG advises that both partners in a couple requesting *assisted conception#* services should be registered with the same general medical practice, or at least with a practice in the same CCG. If a couple do not follow that guidance, then this CCG will normally fund only up to 50% of the cost of any *assisted conception#* service and will expect the other CCG to fund the remainder. Any funding will be subject to the couple (i.e. both partners) satisfying the eligibility criteria in this policy. The other CCG may also impose eligibility criteria.

However, in the event that:

- the only service requested is the storage and/or *transfer#* of *fertilised#* embryos, and
- those embryos have been produced from the eggs of the female *partner#* herself, and
- the female *partner#* is registered with this CCG, and
- other eligibility criteria in this policy are satisfied,

then this CCG may provide up to 100% of the requested funding irrespective of the CCG responsible for the other *partner#*.

2. In the exceptional circumstance of a *patient#* registered with a general practice of CCG A acting as a surrogate to a recipient who is registered with a general practice of CCG B, then this CCG will:

- expect CCG B to provide funding for any healthcare leading to the *conception#* ;
- expect CCG B to provide funding for the clinical management of the surrogate, foetus or baby in relation to the of the pregnancy, pregnancy related conditions, delivery and immediate (up to ten days) postnatal period;
- expect CCG B to provide funding for the clinical management of the situation if the pregnancy becomes unwanted;
- expect CCG A to provide funding for any healthcare unrelated to the *conception#* or pregnancy that may be required by the surrogate at any time;
- expect CCG A to provide funding for any healthcare required by the surrogate beyond ten days after delivery even if that care is related to the pregnancy;
- expect CCG A to reimburse CCG B for any healthcare costs paid that relate to the *conception#*, pregnancy, delivery or postnatal care, in the event of the baby not being passed to the care of the *patients#* within a defined time after delivery.

except that under any circumstance this CCG will offer any funding on an interim basis that it considers necessary to ensure the safety of the surrogate and of the foetus, with a view to reclaiming costs in accordance with this protocol.

This protocol therefore applies when a woman from this CCG is acting as surrogate to

	<p>a recipient from another CCG, or when the reverse applies. This CCG expects this protocol to be agreed between the two CCGs before any treatment commences.</p> <p>3. In the exceptional circumstance of a <i>patient#</i> registered with a general practice of CCG A acting as an egg donor to a recipient who is registered with a general practice of CCG B, then if the donor is offering surplus eggs produced as a result of her own <i>assisted conception#</i> treatment, CCG A would be expected to fund all of her healthcare. However if the donor is producing eggs specifically for the purposes of donation to a particular <i>patient#</i> who is unable to produce her own eggs, then this CCG will:</p> <ul style="list-style-type: none">• expect CCG B to provide funding for any healthcare to the donor in relation to the stimulation of the ovaries, the induction of ovulation and the harvesting of eggs.• expect CCG B to provide funding for any healthcare required by the donor to address any complications resulting from the egg donation process for a period of up to ten days beyond the date of egg harvesting;• expect CCG A to provide funding for any healthcare unrelated to the egg donation at any time;• expect CCG A to provide funding for any healthcare required by the donor beyond ten days after egg harvesting even if that care is related to the donation; <p>except that under any circumstance this CCG will offer any funding on an interim basis that it considers necessary to ensure the safety of the donor, with a view to reclaiming costs in accordance with this protocol.</p> <p>This protocol therefore applies when a woman from this CCG is acting as donor to a recipient from another CCG, or when the reverse applies. This CCG expects this protocol to be agreed between the two CCGs before any treatment commences.</p> <p>4. This CCG will not make any financial contribution to the costs of <i>patients#</i> registered with its general practices who are requesting funding to be sperm donors, either to a bank or to specific recipients who are not registered with one of this CCG's general practices.</p> <p>5. Any statutory or mandatory requirement placed on CCGs may take precedence over the provisions of this appendix.</p>	
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APPENDIX 6		
Pregnancy in older women		
	<p>Current advice from NHS choices is that older women face risks associated with pregnancy. In particular at http://www.nhs.uk/news/2009/06June/Pages/WarningToOlderMothers.aspx they state that:</p> <p><i>“As women get older, both mothers and babies face an increased risk of pregnancy-related complications and health problems. These are due to changes in the reproductive system and the increased likelihood of general health problems that comes with age. Problems include:</i></p> <ul style="list-style-type: none"> • <i>Greater difficulty in initially conceiving a child, with the personal and psychological difficulties that this can cause.</i> • <i>Increased risk of complications for both mother and infant during pregnancy and delivery (although the actual size of the risk may be small).</i> • <i>Greater risk of general maternal health problems, such as high blood pressure, which can contribute to complications.</i> • <i>Higher risk of miscarriage in women above the age of 35.</i> • <i>Higher risk of having twins or triplets, which is itself associated with higher risk of complications.</i> • <i>Increased chance of having a baby with a congenital abnormality, such as Down’s syndrome.</i> • <i>Increased risk of pre-eclampsia.</i> • <i>Increased risk of complications during delivery, such as prolonged labour, need for assisted delivery or Caesarean section, or stillbirth.”</i> <p>Other sources (eg American congress of Obstetricians and</p>	

	<p>Gynaecologists at http://www.acog.org/Patients/FAQs/Having-a-Baby-After-Age-35) offer similar advice.</p> <p>The first bullet point above is relevant to this policy; 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.</p> <p>Bullet points 2, 3, 4, 7 and 8 all describe risks to the mother and / or baby in pregnancy in older women. These risks are relevant to all pregnancies, irrespective of the mode of conception (including natural conceptions, own egg IVF and donor egg IVF). While some older women do accept these risks to achieve natural pregnancies, the CCG prefers to focus its assisted conception efforts to achieve pregnancies that do not carry these risks, and therefore the age cut-off points set in NICE guidance are reflected in this policy, irrespective of the source of the eggs used for the treatment.</p> <p>Bullet points 5 and 6 are included to retain the accuracy and context of the quote but are not the basis for criteria in this policy.</p>	