NHS
Cheshire and Merseyside

Appendix Two

Subfertility Clinical Policy

Other proposed changes to NHS C&M Subfertility policies

Section	Current CCG policies	Evidence-based policy suggestion & proposed policy section	Major changes and Rationale	Impact
3. Definition of Subfertility, Timing of Access to Treatment & Age Range	3.1 Fertility problems are common in the UK, and it is estimated that they affect one in seven couples. 84% of couples in the general population will conceive within one year if they do not use contraception and have regular sexual intercourse. Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate 92%). In 25% of infertility cases the cause cannot be identified. 3.2 Where a woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within twelve months should be taken as an indication for further assessment and possible treatment. In the following circumstances an earlier assessment should be considered: • If the woman is aged 36 or over, then such assessment should be considered after 6 months of unprotected regular intercourse since her chances of successful conception are lower and the window of opportunity for intervention is less. • If there is a known clinical cause of infertility or a history of predisposing factors for infertility. 3.3 Women should be offered access to investigations if they have subfertility of at least 1 year duration (6 months for women aged 36 and over) and offered IVF if they have had subfertility of at least 2 years duration (12 months for women aged 36 and over) Additional criteria apply for IVF in women aged 40 – 42 (see paragraph 12.4). 3.4 If, as a result of investigations, a cause for the infertility is found, the patient should be referred for appropriate treatment without further delay.	4.1 Fertility problems are common in the UK and it is estimated that they affect one in seven couples. Eighty four percent of women in the general population will conceive within one year if they have regular, unprotected sexual intercourse. Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate 92%). In 25% of infertility cases the cause cannot be identified. 4.2 Where a woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within twelve months should be taken as an indication for further assessment and possible treatment. 4.3 In the following circumstances an earlier assessment should be considered: • If the woman is aged 36 or over, then such assessment should be considered after 6 months of unprotected regular intercourse since her chances of successful conception are lower and the window of opportunity for intervention is less. • If there is a known clinical cause of infertility or a history of predisposing factors for infertility. 4.4 Women should be offered MAR treatments if they have had subfertility of at least 2 years duration (12 months for women aged 36 and over) – this includes the initial 12-month period before the initial assessment. Additional criteria apply for IVF in women aged 40–42 (see paragraph 12.6). 4.5 This policy adopts NICE guidance that access to high level treatments including IVF should be offered to women up to the age of 42 years. First treatment cycles must be commenced before the woman's 43rd birthday. 4.6 Women will be offered treatment provided their hormonal profile is satisfactory i.e. in line with NICE CG156.	1. The minimum age (23 years) has been removed as this is no longer supported by NICE. 2. "Before the woman's 42nd birthday" has been changed to "before the woman's 43rd birthday" because this is consistent with NICE. 3. Additional Mersey paragraph (in green) has been deleted – the statements are not supported by the cited references. However, this topic is covered later in section 11. 4. Paragraph 3.3 rewritten to improve clarity/accuracy.	1. NICE withdrew the recommendation for minimum age (23 years) in 2004. 2. Together with the "increase" in upper age from before the woman's 42nd birthday to 43rd birthday, these changes in age limits are unlikely to have a significant impact. 3. The impact on additional costs with increasing this upper age limit has been detailed below **

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	Additional text in Mersey only The CCG will offer access to intra-uterine insemination (IUI) or donor insemination-(DI) services where appropriate after subfertility of at least 12 months duration. See Section 11. NICE guidance recommendations 117 – 119. P223 http://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3 Fertility | Guidance and guidelines | NICE section 1.91 p31 This policy adopts NICE guidance that access to high level treatments including IVF should be offered to women between the ages of 23 – 42 years. First treatment cycles must be commenced before the woman's 42nd birthday (See section 12.4 for further details). Women will be offered treatment provided their hormonal profile is satisfactory i.e. in line with NICE CG156 section 6.3 guidance recommendations.	https://www.nice.org.uk/guidance/cg156 https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453		

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4. Definition of Childlessness	4.1 Funding will be made available where a couple have no living children from a current or any previous relationship i.e. if previous living child from current or previous relationship then excluded from subfertility treatment. 4.2 A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child. 4.3 Once a patient is accepted for subfertility treatment they will no longer be eligible for further treatment if a pregnancy leading to a live birth occurs or the patient adopts a child. Alternative text in E & W Cheshire only 4.3 Where a patient has started a cycle of IVF treatment and they have a pregnancy leading to a live birth, or the patient adopts a child, they can continue to complete this cycle but would not be eligible to start a further new cycle. (E Cheshire / W Cheshire)	7.1 Funding will be made available where a couple have no living children from a current or any previous relationship i.e. if there is a previous living child from a current or previous relationship, then patients are excluded from subfertility treatment. 7.2 A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child. 7.3 Once a patient is accepted for subfertility treatment, they will no longer be eligible for any other MAR treatment or procedures if a pregnancy leading to a live birth has occurred or the patient has adopted a child.	1. Around 75% of ICBs in England and 87% of the former CCGs concur with the evidence-based policy definition of childlessness related to living/adopted children. This definition is not covered by NICE because (presumably) this is a "non-clinical" factor. 2. All 4 current policies carry this same definition in 4.1 & 4.2 and thus are "harmonised". 3. The E & W Cheshire's modified version of paragraph 4.3 suggests that once a pregnancy occurs, the patient can continue using the frozen embryos from the existing cycle. This is unusual, and most policies state that once a woman is pregnant (or adopts a child), the NHS is no longer liable for further treatment. It is also inequitable that some women may receive treatment for more than one child, whereas others are ineligible for any NHS treatment at all.	1. The current and evidence-based policies are in broad agreement with each other and are consistent with the rest of the country. 2. There is unlikely to be a significant impact with regard to the cost to this policy. This will result in reduced activity and therefore a small financial saving. 3. The subject of storage of any remaining embryos following a live birth is covered in section 16.
8. Female and Male Body Mass Index (BMI)	8.1 Women Male and female partners will be required to achieve a BMI of 19-29.9 before subfertility treatment begins. Women outside this range can still undergo investigations, but subfertility treatment will not commence until their BMI is within this range. Alternative text in Wirral only Additional text in green. N.B. Although Wirral is the only CCG which specifies *male and female* patients , E & W Cheshire and Mersey CCGs cite women only in their statements. However, it has to be emphasised that the title in the Cheshire policies is "Female and Male BMI". This could leave the reader in some confusion as to whether the policy applies to men or women.	8.1 The woman intending to carry the pregnancy, will be required to achieve a BMI of 19-29.9 kg/m² before subfertility treatment begins. Women outside this range can still undergo investigations, but subfertility treatment will not commence until their BMI is within this range. 8.2 Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility, and they should be strongly encouraged to lose weight as this will improve their chances of a successful conception.	1. According to NICE, a BMI which is >30 in females has a negative impact on fertility. The chance of a live birth following IVF treatment falls with a female BMI outside the range 19-30. 2. Therefore, it is not unreasonable to withhold treatment until the female BMI is <30. 3. In men, a high BMI may become a consideration especially if male factor infertility is a problem. 4. NICE recommendation of "informing" men that their obesity is likely to have an impact on their fertility was based on the best available evidence at that time (2013).	1. It could be argued that the current CCG policies are so ambiguous that readers will be uncertain whether the BMI restrictions apply to both men and women. Therefore, the proposed policy brings greater clarity.

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9. Female and Male Smoking[1] Status	9.1 Patients (Male and female partners) should be confirmed non-smokers in order to access any subfertility treatment and must continue to be non-smoking throughout treatment. Providers should seek evidence from referrers and confirmation from patients. Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking could result in cessation of treatment. 9.2 It is preferable that couples are not using any nicotine products but if nicotine replacement therapy or e-cigarettes are being used by either person in the couple, this would not exclude fertility treatment. (Wirral, E Cheshire and W Cheshire) Alternative text in Mersey only Additional text in green. Additional paragraph in E & W Cheshire only Text in blue Mersey and Wirral contain paragraph 9.1 only.	**Female and Male Smoking * Status** 9.1 Both partners (i.e. female and/or male) should be confirmed non-smokers in order to access any subfertility treatment and must continue to be non-smoking throughout treatment. Providers should seek evidence from referrers and confirmation from patients. Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking could result in cessation of treatment. *Smoking increases the risk of infertility in women and men. Nicotine alone is known to affect development of the foetus and long-term safety data on e-cigarettes are unknown. Because of these concerns and issues, all forms of smoking (which includes cigarettes, e-cigarettes or NRT) are not permitted.	1. The Mersey policy refers to "patients" (as opposed to *male and female partners*) which suggests that smoking restrictions apply only to the person receiving treatment i.e. the "patient". This ignores the impact of second-hand smoke on the on the offspring and if the partner is also a smoker, the impact of smoking on their fertility. 2. Paragraph 9.2 (in blue) appears in E & W Cheshire policies only and this exempts couples using e-cigarettes and/or nicotine therapy. 3. According to NICE CG156, smoking can adversely affect fertility and the success rates of assisted reproductive techniques (in both men and women). 4. There are significant associations between maternal cigarette smoking in pregnancy and increased risks of small-for-gestational-age infants, stillbirth and infant mortality. 5. Nicotine-containing products (which include e-cigarettes) are not considered to be safe in pregnancy. 6. Whilst current evidence on e-cigarettes suggests these may be less toxic than smoking, long term safety data in the general population are lacking. 7. There is even less data on the impact and safety of e-cigarettes on fertility and on the developing foetus and beyond. 8. In addition, there is increasing concern about the propellants used in e-cigarettes which may be responsible for a number of reported deaths. 9. Because of these safety concerns on the growing foetus and offspring, paragraph 9.2 has been removed.	1. Both partners are now included in the smoking restriction, and this is consistent with NICE guidance. 2. Practically, the rewritten paragraph 9.1 is unlikely to have an impact on activity. 3. Removal of paragraph 9.2 could potentially result in a small number of patients being refused treatment albeit temporarily. However, it remains to be seen whether, in practice, Providers follow this policy for Cheshire patients.

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10. Female and Male Drugs & Alcohol intake	10.1 Patients Male and female partners will be asked to give an assurance that their alcohol intake is within Department of Health guidelines, and they are not using recreational drugs. Any evidence to the contrary will result in the cessation of treatment https://www.gov.uk/government/policies/reducing-drugs-misuse-and-dependence https://www.gov.uk/government/policies/reducing-harmful-drinking **Alternative text in Mersey only** Additional text in green.	10.1 Both partners (i.e. female and/or male) partners will be asked to give an assurance that their alcohol intake is within Department of Health guidelines, and they are not using recreational drugs. Any evidence to the contrary may trigger a pause in treatment with possible referral for a welfare of the child assessment and/or further information sought from the GP. https://www.gov.uk/government/policies/reducing-drugs-misuse-and-dependence https://www.gov.uk/government/policies/reducing-harmful-drinking	1. The Mersey policy applies to the person who is receiving treatment only whereas the other policies apply to all partners whether they are receiving treatment or not. 2. There is evidence that alcohol and recreational drugs reduce the chance of conception in both men and women. Also, there are the well-recognised adverse effects of alcohol on the growing foetus. 3. Required assurances on alcohol/recreational drug intake should, therefore, apply to both partners irrespective of which one is receiving treatment. 4. In addition, the evidence-based policy has been expanded to included situations where the clinician might have concerns about a potential alcohol/drug misuser and if this could have implications for the welfare of the child.	1. Practically, changing the requirement to include both partners in Mersey is unlikely to have an appreciable impact. 2. Providers will be able to confirm that the need for a welfare of the child assessment has always been standard practice.
11. Intra-uterine Insemination (IUI)/Donor Insemination (DI) & Intracytoplasmic Sperm Injection (ICSI)	11.1 In advance of IVF treatment Consider unstimulated intrauterine insemination (to a maximum of 6 cycles) as a treatment option in the following groups as an alternative to vaginal sexual intercourse: • People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or-psychosexual problem who are using partner or donor sperm; • People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive); • People in same sex relationships. 11.2 For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse, do not routinely offer intrauterine insemination, either with or without ovarian stimulation. Advise them to try to conceive for a total period of time as per section 3.3 before IVF will be considered.	11.1 Unstimulated intrauterine insemination is a treatment option in the following groups as an alternative to vaginal sexual intercourse: • People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or-psychosexual problem who are using partner or donor sperm; • People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive); • People in same sex relationships (please see section 5 regarding eligibility and the need for the first 6 cycles to be self-funded). 11.2 For people in 11.1 above who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, should be offered a further 6 cycles of unstimulated intrauterine insemination before IVF is considered.	1. Policies in Mersey, E & W West Cheshire are very similar with minor differences in wording. 2. The main difference is that paragraph 11.5 is missing in the Cheshire policies. This details the number of IUI cycles required before treatment and is consistent with NICE. 3. Paragraphs 11.1, 11.2 are closely aligned to current NICE recommendations. 4. The Wirral “no commission” policy is of grave concern as it contradicts current NICE guidance and is open to legal challenge. 5. Overall, the best representation of the NICE guideline is provided by the Mersey policy. The evidence-based policy, therefore, is largely based on this and has been expanded to include more appropriate recommendations from NICE. 6. For example, the new paragraph 11.4 on donor insemination are all NICE recommendations. 7. For same sex couples and single women (in 11.1), reference is made to section 5	1. With the exception of Wirral’s “not routinely commissioned” stance, the evidence-based policy is based on the Mersey/Cheshire policies and has been revised to improve clarity and include some additional NICE recommendations. 2. There is unlikely to be an appreciable change in access. 3. Only Providers can confirm whether they have rigidly adhered to the Wirral policy in the past. If they have there will be a number of patients who will now be

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	11.3 Donor insemination (with IUI) will be funded where clinically indicated. 11.4 Stimulated IUI will be funded where clinically indicated, due concern must be given to the risk of multiple births in this situation and insemination abandoned if this is felt to be a possibility. 11.5 Patients who are receiving IUI who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, should be offered a further 6 cycles of unstimulated intrauterine insemination before IVF is considered. (NB this paragraph has been deleted in the Cheshire policies) 11.6 Patients who fail to achieve a pregnancy using IUI/DI will be considered for IVF. Alternative text in E & W Cheshire 1. Additional text in green. 2. Also note that paragraph 11.5 has been deleted in both Cheshire policies. **Section 11 Wirral only** **NB** Policy statement is "not routinely commissioned" for **ALL** of the above.	11.3 For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse, do not routinely offer intrauterine insemination, either with or without ovarian stimulation. Advise them to try to conceive for a total of 2 years (or 12 months for women aged 36 and over) as per section 4 before IVF will be considered. 11.4 Donor insemination (with IUI) may be funded for the following indications:- • obstructive azoospermia • non-obstructive azoospermia • severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection (ICSI). • high risk of transmitting a genetic disorder to the offspring • high risk of transmitting infectious disease to the offspring or woman from the man • severe rhesus isoimmunisation 11.5 Stimulated IUI will be funded where clinically indicated, due concern must be given to the risk of multiple births in this situation and insemination abandoned if this is felt to be a possibility. 11.6 Patients who fail to achieve a pregnancy using IUI/DI will be considered for IVF. 11.7 For the sake of clarity, according to CG 156, 12 months of unprotected vaginal intercourse is considered to be equivalent to 6 cycles of artificial insemination. Further, the usual requirements for women aged ≥ 36 years are halved (in comparison to women aged <36 years) i.e. they may be required to experience a period of "watchful waiting" of 6 months (as opposed to 12 months in younger women) and/or to undergo 3 cycles of artificial insemination (as opposed to 6 cycles in younger women). 11.8 Intracytoplasmic Sperm Injection (ICSI) is routinely funded for:- • severe deficits in semen quality or • obstructive azoospermia or • non-obstructive azoospermia.	which specifies the need for self-funding of the first 6 cycles of artificial insemination. 8. The need for self-funding is discussed in more detail in section 5 above.	eligible for this treatment. However, our data shows that this will be minimal. Liverpool Women's Hospital data shows 56 cycles for 19 patients over a period of 6 years were completed. Care Fertility reported 0 IUI's over this same period.

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Overseas Visitors eligibility for NHS-funded IVF treatment	This is a new section and does not appear in any of the existing CCG policies.	6.1 An individual ordinarily resident in the UK is eligible for NHS funded fertility treatment. 6.2 Overseas visitors coming to, or remaining in, the UK for six months or more are usually required to pay the immigration health charge (referred to as the health surcharge, or IHS) unless an exemption from paying the surcharge applies or the charge is waived. 6.3 IVF is excluded from the list of NHS treatments overseas visitors can access, even if the above surcharge is paid. 6.4 Where a non-resident wishes to access IVF, they should be charged 150% of the National NHS tariff (or locally agreed price where applicable). IVF treatment charges should be made in advance of any treatment being given. 6.5 If care is deemed an emergency by the Fertility Consultant, the provider and ICB can enter a risk share scheme and split 50% of the costs each. 6.6 Current Guidance on Overseas Visitors and Eligibility can be found using the following link https://www.gov.uk/government/publications/nhs-cost-recovery-overseas-visitors.	1. This is a new section which has been written in conjunction with Liverpool Women's Hospital Overseas Visitors Team.	1. Although this section is new, the guidance on overseas visitor's access to fertility treatment is the same as the current position, it is just not called out in the policies.
16. Storage and cryopreservation of embryos, oocytes (eggs) and semen	19.1 Embryo, egg and sperm storage will be funded for patients who are undergoing NHS subfertility treatment in line with The Human Fertilisation and Embryology Authority guidance. The storage standard period for sperm, egg and embryo storage is normally ten years (subject to 4.3) **Additional text for E & W Cheshire** Additional text in green **Section 22: Cryopreservation** 22.1 Cryopreservation services in line with the relevant principals outlined in NICE IPG 156 Section 1.16 will be offered to: Women with premature ovarian failure under the age of 40 (see previous definition - see section 17).	17.1 Storage of embryos, oocytes or semen is routinely commissioned for eligible patients who are undergoing NHS subfertility treatment. Readers are required to interpret this section in conjunction with the ICB policy on "Childlessness". **Fertility Preservation before treatment for cancer (or other procedures which affect fertility)** 17.2 Cryopreservation of embryos, oocytes or semen is routinely commissioned before treatments or procedure (e.g. for cancer or other medically essential interventions such as a surgical procedure and/or administration of medication) which are known to affect fertility. This will be performed in accordance with the Human Fertilisation and Embryology Authority (HFEA) regulations and NICE guideline CG 156.	1. This section has been completely redrafted and combines sections 19 & 22. 2. It more accurately reflects the recommendations from NICE on this topic. 3. Strictly speaking, CG 156 recommends cryopreservation for patients about to receive treatment for cancer. However, reading the full guideline version, it is clearly apparent that the intention of the guideline committee was to provide cryopreservation for any treatment which could affect fertility. 4. Thus, paragraph 19.2 specifies cancer but also treatment for "other medically necessary interventions"	1.There is unlikely to be any cost implications for cryopreservation as this storage limit hasn't changed. 2. LWH finance colleagues have confirmed they are comfortable with all proposed changes and there is no significant financial impact.

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	Men and women with cancer, or other illnesses which may impact on fertility, may access tertiary care services to discuss fertility preservation (egg, embryo or sperm storage). Other illnesses are not defined in this policy but will be considered on an individual basis via an Individual Funding Request. Storage will be in-line with section 19. 22.2 The eligibility criteria set out in this policy do not apply to cryopreservation but do apply to the use of the stored material. 22.3 Storage of ovarian tissue will not be funded.	17.3 Patients must satisfy the prevalent subfertility criteria when the time comes to use this stored material and they must have been informed of this requirement before commencing cryopreservation. 17.4 The cryopreserved material may be stored for 10 years or up to the female partner's 43rd birthday, whichever comes sooner. **Following a live birth** 17.5 The ICB will fund up to 12 months' storage following the birth or adoption of a child (i.e. a "grace" period) to give the patient enough time to decide whether they wish to self-fund, donate the stored material or consent to having any remaining gametes or embryos destroyed. 17.6 This is in accordance with the ICB's policy on "Childlessness" and beyond the "grace" period, funding for storage will no longer be available. **18 Storage of Ovarian Tissue** 18.1 Storage of ovarian tissue is not routinely funded.	which is more in keeping with CG 156. 5. Patients will need to be confirmed as sub-fertile when the stored material is being used according to CG156 (recommendation 1.16.1.6) 6. The Working Group discussed the length of storage for a number of situations. 7. For cryopreservation, a period of 10 years was agreed, and this is consistent with the existing policy. 8. Section 17.5 'Following a live birth' was added to the policy at the request of the fertility experts on the working group. 9. The group were advised that a 6 – 12 months' storage period is standard for this situation.	

** Definition of Subfertility, Timing of Access to Treatment & Age Range - Impact

The graph below shows the IVF split over the past five years. It suggests that women aged 42 make up about 2% of all IVF activity at LWH. There's a clear pattern where the uptake increases from 29 onwards, peaking at age 34. It then starts to drop-off again gradually to 41, when it falls of steeply at age 42. Therefore, the impact of increasing this upper age limit by a year will have minimal impact on activity and costs.