# SCHEDULE 2 – THE SERVICES

1. **Service Specifications**

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| Service Specification No. | IVF Service Specification v 2 |
| Service | Assisted Conception Service |
| Commissioner Lead | Merton & Wandsworth Clinical Commissioning Group |
| Provider Lead |  |
| Period | 1 April 2019 — March 2022 (Plus extension 1 year) |
| Date of Review | September 2018 |

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| **1. Purpose** |
| The purpose of Specialist Fertility is to provide a range of appropriate assisted conception services for couples who meet the eligibility criteria.   * 1. **Aims**   To provide a quality, safe, cost effective assisted conception service ensuring that the risk of infection and other complications to Service users is minimised.  To provide a personal service sensitive to the physical, psychological and emotional needs of Service users.  To ensure effective communications between Service users and the service providers.  To ensure effective communication between commissioners and the service providers.  To ensure effective communication between Referrers (GP/ Secondary care clinicians/ etc.) and the service providers.  To develop and implement a data collection and monitoring processes which provides fertility services intelligence to support the future commissioning of fertility services.   * 1. **Evidence Base**   Merton & Wandsworth CCG only commission fertility techniques regulated by the Human Fertilisation and Embryology Authority (HFEA).  This specification is designed to sit alongside the legislative provisions of Infertility treatment and the Care Standards Act, and is not designed to replicate these provisions, or to duplicate, replicate or supersede the following policies and guidelines, which may change over time:   * The Human Fertilisation and Embryology Act; 1990 * The National Institute for Clinical Excellence Infertility guidance (CG156 - “Fertility: assessment and treatment for people with fertility problems”); 2017 * The East of England Fertility Services Commissioning Guidelines; 2013 * National Minimum Standards for Independent Healthcare; 2000 * Any Quality standard as determined by the Care Quality Commission * Any Quality standard required under the terms of the Care Standards Act; 2000 * Ethnicity * Disability Discrimination Act; 2005 * Equality Act 2010   **1.3 General Overview**  This service provides Specialist Fertility treatment for the Merton & Wandsworth Clinical Commissioning Group.  **1.4 Objectives**   * To offer Specialist Fertility Services which are safe, effective, appropriate, accessible and acceptable to Service users, and represent good value for money * To offer Specialist Fertility treatment in line with the care pathway agreed by the CCG   To offer Service users consistent, appropriate and suitable information in a format that they can understand.  **1.5 Expected Outcomes**   * Improved access to Specialist Fertility services for all patients who have need and qualify for treatment under conditions stated below. * To be among the top 25% of providers for live birth rates * Achieve a 40% or higher live birth rate for women aged up to 37 years * Achieve a 20% or higher live birth rate for women aged between 38 years and 39 years * Achieve a 15% or higher live birth rate for women aged between 40 years and 42 years * Reduction in the annual multiple-birth rate to 10% or below * Reduction in the onward transmission of chronic viral infections such as Hep B, Hep C and HIV |
| **2. Service Scope** |
| **Merton & Wandsworth residents will receive treatment in line with NICE guidelines, the Department of Health recommendations and CCGs Assisted Contraception Policy 2014/15.**  **2.1 Service Description**  The specialist fertility services to be provided to patients fulfilling the eligibility criteria include   * In Vitro Fertilisation (IVF), * Intra-cytoplasmic Sperm Injection (ICSI) * Intra Uterine Insemination (IUI) Unstimulated. * Intra Uterine Insemination (IUI) Stimulated- Funded on an exceptional basis   Surgical sperm retrieval methods including micro-epididymal sperm aspiration (MESA), testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA) and micro TESE. Funded on an exceptional basis, subject to CCG policies.   * Egg, sperm, embryo and gonadal tissue cryo storage and replacement techniques and other micro-manipulation techniques * Egg donation where no other treatment is available. The patient must be able to provide a donor; alternatively, the patient can be placed on the waiting list until a donor becomes available. This waiting list will be monitored separately to the general IVF waiting list and will not be subject to an 18-month maximum waiting time. * Donor insemination in following conditions obstructive azoospermia, non-obstructive azoospermia, severe deficits in semen quality in couples who do not wish to undergo ICSI, where there is a high risk of transmitting a genetic disorder to the offspring, where there is a high risk of transmitting infectious disease to the offspring or woman from the man. Blood borne viruses (ICSI and sperm washing) as per NICE guidance (section 1.3.9) Sperm washing not offered as part of fertility treatment for men with hepatitis B.   The above services are provided in line with NICE clinical guidelines 2013 and HFEA regulations  **This service agreement does not cover:**  The referral of couples by the secondary Provider to the tertiary Providers, who have not had the prerequisite investigations or treatments required, at either the primary level or secondary level. The referral letter will need to include information such as any investigations, information on patients and clearly state whether the patient is eligible for specialist treatment.  **2.2 Accessibility/acceptability**  The Provider will ensure that, in conjunction with the eligibility criteria set out in section 4.3 (Referral criteria and sources), its services are accessible regardless of age, disability, race, culture, religious belief, sexual orientation, gender identity or income levels. The Provider will deal sensitively with all Service users, potential Service users and their family/friends and advocates.  **2.3 Interdependencies**  The Tertiary service Provider will work directly with the following professionals to ensure a seamless service and the continuity of holistic care:   * General Practitioners * General Practitioners with Special Interest * Referring Secondary Provider Clinical Leads and Fertility Nurses * Clinical Commissioning Group * Exceptionality Clinical Review Boards * NHS Genetic Services   **2.4 Relevant networks and screening programmes**  All Providers must be licensed by the Human Fertilisation and Embryology Authority (HFEA). Core skills and competencies of Staff are set by the HFEA as the regulatory authority for tertiary fertility services.  In addition Providers are expected to comply with relevant legislation, including Health and Safety requirements, and to follow best practice guidelines. |
| **3. Service Delivery** |
| **3.1 Service model**  **3.1.1 Principles of Care**    The assisted conception service offered will be safe, effective, appropriate, accessible and acceptable to Service users and represent good value for money.  Clinical management of eligible couples should be in line with the agreed local care pathway. This is based on the NICE clinical practice algorithm as modified by individual CCG policies. This local pathway identifies the tests and treatments to be undertaken within Primary (level 1), Secondary (level 2) and Tertiary care (level 3). Within the pathway test results should be passed on and not duplicated.  Where clinically appropriate, waiting times should conform to the 18-week pathway, which begins when a patient is referred from a specialist service to tertiary, and is considered eligible based on the relevant criteria. Service users should be seen in the chronological order of admission on waiting lists and informed of their acceptance on the waiting list.  The Provider will co-ordinate Inpatient, day care and outpatient services to ensure continuity of care.  Couples should be seen together because both partners are affected by decisions about investigations and treatment and to allow them to participate in planning their care. They should be seen in a comfortable environment ensuring privacy and dignity.  Couples should be treated by a specialist team to improve the effectiveness and efficiency of treatment and outcomes. Service arrangements with Tertiary Specialist Providers will be via a specific contract identified by OCCG.  Couples should be provided with consistent, appropriate and suitable information in a format that they can understand. This information will be provided by the specialist Centre.  The Provider will ensure that the Service user is afforded the right to be fully informed of their condition, if they so wish, and to ensure information is communicated in an understandable and sympathetic manner.  Couples should be offered counselling prior to, during and after assessment or treatment irrespective of the outcome of that treatment, from someone independent of the treatment team, the cost for which will be met by the Tertiary Provider.  Couples should be informed that they may find it helpful to contact a fertility support group and information should be made available on how to access the support group www.infertilitynetworkuk.com  **3.1.2 Service Requirements**  The Provider will ensure that the Fertility services, where appropriate are shaped around the preferences of Service users, their families and their carers.  Service users will be treated with respect and their dignity to be safeguarded regardless of age, , gender, ethnicity, religion, culture and sexuality.  Services provided should be culturally sensitive. Where appropriate, the Provider will work in partnership with other organisations to promote the delivery of a seamless service.  All staff will respect the confidentiality of the Service user as required by the NHS document: The Care Record Guarantee (Department of Health, 2007). The Provider will be responsible for asking the patient to sign a confidentiality release clause to share treatment data to the funding authority.  The Provider will offer the Service user an appropriate and timely first Outpatient Appointment from the initial referral from the secondary or primary care provider.  Hospitalisation will normally be dealt with on a day case basis. If, however, this requires to be extended for clinical requirements, for a maximum of 24 hours, no further charge will be raised.  If the length of stay is likely to be extended more than 24 hours the Tertiary Provider must contact the on-call gynecologist at the nearest District General Hospital to discuss appropriate management. This may require the Service user to be transferred to an appropriate District General Hospital.  Should emergency re-admission be required within 30 days, as a result of complications arising as a direct result of the initial clinical operative procedure, this will be absorbed as part of the initial episode of care to a maximum of five days.  The Provider will offer a 5-day normal working hours service, with the ability if necessary, to provide services up to seven days, in addition to an out of hours emergency contact details.  Service users will be offered counselling with a Specialist Fertility Counsellor in line with the HFEA Code of Practice.  Information sheets in non-technical language should be available to explain the proposed investigations and treatment, including detailed information on drugs (and any possible side effects) prescribed by the Centre and clear information about potential complications of treatment with signs to look out for and appropriate emergency/ information contact details. Information should be tested out with couples to ensure it is user-friendly and available in a range of languages.  Information relating to outcomes should be available for couples on request.  Information to Service users should make it clear that if the treatment Centre does not receive contact from the couple for a six-month period they will be removed from the list.  The Tertiary Provider will confirm the removal from the list by written communication to the named Fertility Services Contracts Manager at OCCG with a copy sent to the Service user, the Service user’s GP and referring consultant from the secondary provider.  It is the responsibility of the Provider to bear the cost of all ultrasound scans and any additional outpatient appointments, which may include other tests or observations, until the woman is referred by her GP to the maternity services.  **3.1.3 Treatment Details**  For continuity of care delivery, the Service user will have a named Lead Clinician, who will take responsibility for the Service user during this pathway of care.  Referral criteria and sources are listed in section 4.3 of this document. It is the responsibility of the commissioned provider to ensure all criteria are met, all relevant investigations are completed, and the specific number of fresh cycles and embryo transfers allowed to be funded by the referring CCG, has been applied.  The provider must adhere to the following local policies:   * CCG Policy Statement Assisted Conception Policy 2014/15 * Assisted Reproduction Service, Policy Statement 11g – summary of the rationale behind departing from NICE guidelines)   Any previous full IVF cycles, whether self- or NHS-funded **at any IVF provider including those outside the UK**, will count towards the total number of full cycles that a couple may receive under NHS funding by the individual CCG.  A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).  This will include the storage of any frozen embryos for 1 year following egg collection.  Storage (cryopreservation) of surplus embryos following a fresh cycle of NHS-funded IVF and the cryopreservation (freezing and storage) of good quality embryos will be funded for one year to enable couples to have the option to use the frozen-thawed embryos in subsequent treatment.  Patients should be clearly advised at the start of treatment of the level of service available on the NHS (see eligibility criteria for full clarity) and that following this period continued storage or further treatment must be funded by them.  An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.  For couples where the woman is under 35 years of age, there should be a six-month period between completion of the pregnancy test post embryo transfer and commencement of drugs for the fresh cycle.  In the event of abandoned cycle please see Appendix 1.  Should an attempted fresh cycle be abandoned the reason must be recorded in the context of:   * Poor/over ovarian response * Poor fertilisation * Poor embryo quality * Poor Service user compliance   If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first three calendar year of the retrieval date, is the responsibility of the couple.  **Treatment will include**:  Initial consultation follow up consultation, and counselling sessions  It is expected that providers will have a named lead clinician who is known to the patient who will take responsibility for ensuring the patient receives continuity of care during the IVF care pathway  All ultrasound scans and hormone assessments during the treatment cycle.  Oocyte recovery - by vaginal ultrasound guided by aspiration under sedation or local anaesthesia or laparoscopy as appropriate. General anaesthesia will be provided when necessary.  Embryo, or blastocyst transfer, into uterine cavity.  All embryology including sperm preparation and sperm retrieval where indicated.  Embryo/blastocyst freezing, and storage will be commissioned as part of the service requirement and will be funded for up to 3 years following completion of NHS Treatment, when further discussions with the couple will need to take place.  A pregnancy test and a maximum of two scans to establish the viability of the pregnancy.  **3.1.4 Drug Prescribing**  The commissioned provider of the IVF service under this contract will prescribe and supply the necessary drugs.  Accurate and detailed information of the drug, the dosage and the frequency and possible side effects will be given to the Service user including:   * Possible drug interactions * The risk of Ovarian Hyper Stimulation Syndrome (OHSS) * The risks associated with multiple pregnancies * Follow-up and monitoring arrangements, and how the consultant will monitor the woman’s progress * The circumstances under which treatment should be stopped or re-referral made to the secondary provider consultant * The Tertiary Provider consultant will retain overall clinical responsibility   In accordance with HFEA guidelines, the provider will seek the consent of the Service user to relevant information being shared with the registered GP.  Subject to the above recommendations being followed, the cost of this prescribing will be part of the contract.  In line with NHS regulations, prescribing costs for residents receiving IVF on a private basis will not be funded under the NHS.  **3.1.5 Service users Reports**  The tertiary provider will provide a formal written report to be sent to the referring Clinical Lead from the referrer, with a copy to the Service user and their GP within 5 working days of the first consultation, out-lining clinical findings, plan of care and waiting list status.  Following the Service user’s first outpatient consultation, a written report will be sent to the Service user’s referrer, copied to the Service user and their GP.  Robust records of treatment given, and treatment outcomes and pregnancy outcomes must be recorded against the woman’s NHS number.  **3.1.6 Information & Data Requirements**  In order to achieve accurate forecasting, activity monitoring and prompt and accurate payment, there needs to be timely regular exchange of detailed and accurate information. The Provider will provide the information as requested, in the format requested and to the agreed timescales. The Provider, in addition to the Information requirements set out below, will also provide upon request any additional information that the Commissioner may request.  **3.1.7 Standard minimum dataset information**  The Provider will be required to submit standard minimum datasets via SUS which comply with guidance relating to clinical coding published by the NHS Classifications Service and with the definitions of activity maintained under the NHS Data Model and Dictionary. Timescales for provision of this data will comply with those specified by SUS and the Standard NHS Contract for Acute Services.  **3.1.8 Activity and financial monitoring information**  The Provider will produce activity and financial summaries monthly which will give an overview of the performance of the contract for that month and for the year-to-date.  **3.1.9 Monitoring of performance targets and other outcome measures**  The Provider will provide regular monitoring information on a range of performance and outcome measures, including those outlined in sections 3.1.12 and 3.1.13.  The Provider will also provide regular status reports on each couple referred for treatment, which will include details of the treatments-to-date.  **3.1.10 Information Governance**  The provider shall conform to the Data Protection Act, (Department of Health, 2006)  **3.1.11 Quality of Information**  The Provider will ensure that all data provided is complete, accurate and timely.  The Provider will ensure that its staff do not adopt, desist from any current clinical protocol, practice or procedure, or any administrative (or coding) practice or procedure, which will either intentionally or inadvertently, maximize income to the Provider, rather than to reflect the actual necessary treatment received by a Service user, or a group of Service users.  **3.1.12 Performance Targets**  The Provider will comply with current performance targets as laid down by the Department of Health and any local additional performance targets defined by the CCG.   * 18-week pathway for Fertility services * It will be the responsibility of the Provider to identify, in a timely fashion inadvance of the occurrence, any Service user where the performance targets andmaximum waiting times as identified within the this document cannot be met bythe Provider. The provider will then agree with the CCG, the necessary actions toremedy these breaches of the service management. * All tertiary providers will have an elective Single Embryo Transfer (eSET)Strategy, inclusive of selection criteria, asper HFEA requirements.   **3.1.13 Outcomes**  Regular meetings will be held to review the service and improve on any aspects of the service as required (not less than every six months)  **3.1.14 Service user Satisfaction**  Using the HFEA Service user questionnaire, the Provider will give regular feedback to the  CCG, on the recommendations and action plans of these audits.  **3.1.15 Complaints**  The Provider must establish a written complaints procedure. The procedure must incorporate the following:   * A nominated person within the organisation to be responsible for handling complaints; * Complaints must be acknowledged within 2 working days; * A full response or holding letter, signed by the Chief Executive or equivalent, to be sent within 20 working days; * The CCG may wish to conduct an Independent Review Panel Investigation if they are dissatisfied with the Provider's response.   **3.1.16 Waiting times for Tertiary Service Provision**  There will be no user waiting over 18 weeks from referral to the commencement of treatment unless there are mitigating medical circumstances  The service will work towards reducing waiting times below these levels to achieve and improve upon the national standards.  **3.1.17 Clock Stops as per the Department of Health 2008 18-week pathway for fertility services i.e. when the procedure starts**   * Gonadotrophin stimulation of hypogonadal men * Treatment for pituitary tumours and other medical conditions discovered * For IUI, IVF, ICSI, PGD as above if cycle control issues take time or if the Service user is not ready the clock can be stopped. The clock stop is the first day of the menstrual cycle in which the assisted conception is to start. * Service users waiting for egg/sperm donation: the clock stops once they are put on the waiting list (as per transplant lists) * Post-surgery in the event of a miscarriage/ectopic pregnancy * Ovarian Hyperstimulation Syndrome (OHSS) * Active monitoring will begin once the Service user is on a recognised local protocol.   **3.1.18 Outcome Data**  Information on the Provider’s activities will be provided on a quarterly basis, submitted by week 5 of the quarterly end, as follows:  **Basic outcome data**   * Number of couples seen * Number of couples treated * Implantation rates per embryo transfer (IVF) * Implantation rates per cycle of per blastocyst transfer * Live birth rates per embryo transfer treatment cycle * Clinical pregnancy rate – singleton and multiple   **Implantation rates and live birth rates by:**   * Age bands 23-24, 25-29, 30-35, 36-39,40-42 * Diagnostic group * GP and Postcode   **Complications**   * Twin/multiple clinical pregnancy rate. * Twin/multiple births per treatment cycle. * Ectopic pregnancies per treatment cycle. * Rate of Ovarian Hyper-stimulation Syndrome (OHSS) – severity and duration of hospitalisation * Other adverse outcomes needing inpatient management   **3.1.19 Facilities and Equipment**  The provider will be required to show evidence that all equipment used is regularly maintained to a standard commensurate with the needs of the service.  The building/ estate where the service is delivered must be CQC compliant.  **3.1.20 Service Agreement Management**  The provider and the lead commissioner will nominate a contract manager who will be responsible for the operation of the service agreement. This contract manager is to be available to the lead commissioner, or the provider, during normal working hours.  Where due to sickness, absences or annual leave the contract manager is unavailable, then the lead commissioner and the provider will identify a suitable replacement officer who will be able to provide assistance to the other party in any enquiry regarding this service agreement, or its operations.  **3.2 Care Pathways**  The Care pathway route is detailed in Appendix 2. Referrals that do not adhere to this pathway should not be accepted and returned to the originating referrer. |
| **4. Referral, Access and Acceptance Criteria** |
| * 1. **Geographic coverage/boundaries**   The Provider will provide assisted conception services for couples who are registered with a member GP practice of the CCG, and who have been referred by named GPSI’s and Consultant Gynaecologists.  Referrals from NHS Trusts will be accepted, provided that the couples are registered with a member GP practice of the CCG, meet the eligibility criteria set out within this specification, and the appropriate diagnostics have been completed.   * 1. **Days/Hours of operation**   Monday, Tuesday, Wednesday, Friday 07.15am – 17.00pm  Thursday 07.15am – 20.00pm  Saturday 08.00am – 12.00pm   * 1. **Referral criteria & sources**   Referrals for Infertility treatment must be from the following pathways;   * Referral from GP (Primary Care) following primary investigations to secondary provider services. * Referral from the Secondary Provider service named Gynaecologist or GPSI, following on from a diagnosis of infertility. Secondary investigations and/or treatments to have been undertaken (see Criterion number 14 – minimum investigations)   Self-referrals or from any other source than those detailed above will not be accepted and the Service user should be directed back to their GP.  Couples will be assessed for referral using the following referral criteria as per CCG Policy.  The following information must be checked against the relevant policy:   |  |  |  | | --- | --- | --- | | **Criterion** | | **Description** | | 1 | Ovarian Reserve Testing use one of the following:   * FSH | To be eligible, the patient should have an FSH within 3 months of referral and day 2 of the menstrual cycle of <8.9IU/L | | 2 | Maternal age | Following referral to a specialist assisted reproduction service (before the woman’s 35th birthday), treatment must be completed within six months. | | 3 | Paternal Age | There is no upper age limit for the male partner | | 4 | Minimum / Maximum BMI | Between at least 19 and up to 29.9. Patients outside this range will not be added to the waiting list and should be referred to their referring clinician and/or general practitioner for management if required. | | 5 | Duration of sub-fertility | Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet all the other eligibility criteria, will have immediate access to NHS funded assisted reproduction services, including IVF/ICSI. All other couples, including those with unexplained infertility, must have infertility for at least two years’ duration, including one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted reproduction services. | | 6 | Previous Fertility treatment:  Women <35 years | NHS treatment limit will be determined by local CCG policy (1 fresh cycle of IVF, or IVF with ICSI)  Any previous NHS-funded fresh cycles of IVI/ICSI treatment is an exclusion criterion. Couples who have previously self-funded treatment are eligible for one NHS-funded cycle as long as they have not undertaken more than two self-funded fresh cycles. The outcome of the previous self-funded IVF treatment will be taken into account when assessing the likely effectiveness and safety of any further IVF treatment.  Couples will be eligible for NHS funding of one fresh cycle of IVF or ICSI.  Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the CCG will fund 12 months of cryopreservation of the remaining embryos.  If the initial embryo transfer does not result in a live birth, Merton CCG will then fund a single unstimulated frozen embryo transfer   Where couples have self-funded previous cycles, these must not exceed one  Couples will not be eligible for treatment if they have received any previous NHS funded treatment  Women who are aged over 40 but less than 42 at the time of treatment will be entitled to one cycle of IVF/ICSI treatment provided that they have not undergone any previous self-funded or NHS IVF/ICSI treatment previously | | 7 | Current Fertility Treatment  Women <35 years | NHS treatment limit will be determined by local CCG policy and will be available for one cycle of IVF/ICSI treatment per eligible couple. If this cycle has to be abandoned (for whatever reason) after the initiation of ovarian stimulation, the couple will not be eligible to start another NHS funded cycle.  Couples eligible for NHS-funded IVF/ICSI can have only embryos from their NHS funded fresh cycle transferred with NHS funding; the transfer  of frozen-thawed embryos from previous cycles of IVF will not be funded.  If a couple has had frozen-thawed embryos transferred as part of earlier self-funded treatment, the number of frozen cycles will not be included when assessing eligibility for NHS-funded IVF/ICSI. | | 8 | Smoking Status | Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment  Where either of a couple smokes, only couples who agree to take part in a supportive and successful Programme of smoking cessation with Carbon Monoxide verification as an evidence of non-smoking status will be accepted onto the IVF treatment waiting list.  Both partners should have been non-smokers for at least six months prior to commencement of treatment | | 9 | Parental Status | Couples are ineligible for treatment if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships. | | 10 | Previous sterilisation | Ineligible if previous sterilisation has taken place (either partner), even if it has been reversed. | | 11 | Child Welfare | Providers must meet the statutory requirements to ensure the welfare of the child. This includes HFEA’s Code of Practice which considers the ‘welfare of the child which may be born’ and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents. | | 12 | Medical Conditions | Treatment may be denied on other medical grounds not explicitly covered in this document. | | 13 | Residential Status | All Service users must be registered with a member Primary Care Practice of the CCG | | 14 | The cause of Infertility | Couples, including those with unexplained infertility, must have infertility of at least two years’ duration, including one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted reproduction services.    Couples must have been appropriately investigated  There is no criterion for couples with a diagnosed cause of infertility – see below:   1. Tubal damage, which includes:  * Bilateral salpingectomy * Moderate or severe distortion not amenable to tubal surgery  1. Premature Menopause 2. Male factor infertility 3. Ovulation problems adequately treated but not successfully treated i.e. no successful pregnancy achieved 4. Endometriosis where Specialist opinion is that IVF is the correct treatment 5. Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply) | | 15 | The minimum investigations required prior to referral to the Tertiary Centre are: | Female:   * Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate * Rubella antibodies * Day 2 FSH, LH and Estradiol * Chlamydia screening * Hep B and Hep C and HIV status   Male:   * Preliminary Semen Analysis and appropriate investigations where abnormal (including genetics) * Hep B and Hep C (should have been checked within the last 2 years) * HIV status | | 16 | Pre-implantation Genetic Diagnosis | PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service. | | 17 | Rubella Status | The woman must be rubella immune | | 18 | Virology Status | Where one partner or both has a positive diagnosis of HIV, Hepatitis B or Hepatitis C, referral should be made through the Consortium which has already placed a contract for these couples. |     **Same sex couples and women not in a partnership**  IVF treatment will be funded for same sex couples or women not in a partnership if those seeking treatment are demonstrably sub fertile and have undergone a period of expectant management. Same-sex couples should have access to IVF on equivalent grounds to heterosexual couples.  They would first need to demonstrate subfertility through 6 self-funded attempts at artificial insemination using donor sperm in a clinical setting and undergo a period of expectant management involving up to a further 6 cycles of self or NHS-funded donor intra-uterine insemination (see policy statement 4). In this respect, failure to conceive after six cycles of self-funded artificial insemination has been deemed an equivalent indicator of subfertility, given clinical and practical considerations  Note: Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy.  The CCG will not fund surrogacy arrangements. However, when a pregnancy does not occur through surrogacy after 6 cycles of self-funded intra-uterine insemination in a clinical setting there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment. In the case of same sex couples where only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner. The other criteria for eligibility for IVF will also apply.   All same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available  IVF and ICSI services for trans or non-binary people who request IVF and meet all local CCG eligibility criteria are included. The individual will be expected to be able to contribute genetic material to the creation of the baby; i.e., in the case the individual is unable to contribute gametes (eggs or sperm), their care is excluded from being covered by this service specification.   * 1. **Referral route**   The Provider must ensure that the correct referral route is followed. This is set out within section 3.2 Care pathways.  The referral must be within the scope of the Fertility services 18-week pathways as per the Department of Health 2008 – [www.18weeks.nhs.uk](http://www.18weeks.nhs.uk).   * 1. **Exclusion criteria**   Treatment will not be offered to Service users where the referral has been initiated from a non-approved source or where the couples do not meet the referral criteria as set out in section 4.3 – Referral Criteria and Sources.  Sperm washing for virally discordant couples   Surgical sperm retrieval (funded by NHS England Specialised Commissioning)   Add on technologies which do not form part of the National Institute of Clinical Excellences (NICE) recommendations in Clinical guideline (CG)156 (Fertility problems: assessment and treatment), such as endometrial scratching or embryo glue   Anti Mullerian Hormone (AMH) testing: a single test/result should be used in conjunction with other criteria to assess whether a woman is a suitable candidate for IVF. Repeated testing is excluded from this bench mark price due to a lack of clinical evidence of the effectiveness of multiple testing   Short term “back up” sperm freezing for men with male factor infertility- it is anticipated in the small number of men whose sperm count is highly volatile and not consistently suitable for insemination purposes, it is expected providers will take a clinically effective approach. This should not attract an additional price  Donor gametes: the cost of donor eggs or sperm is excluded  Fertility preservation for medical conditions such as cancer are out of the scope for this service specification   * 1. **Response time & detail and prioritisation**   The referral letter from Secondary Provider to tertiary provider must be responded to within 5 working days with   * An acknowledgement to the GP * A first outpatient appointment (OPD) sent to the Service user   Treatment will commence as soon as possible, determined by the woman’s menstrual cycle.   * 1. **Location of Provider Premises**  |  | | --- | | xx |   ( must be CQC inspected and compliant) |
| **5. Transfer of and Discharge from Care Obligations** |
| Discharge from the Tertiary Provider service will occur before the completion of a maximum of 6 embryo transfers or one fresh cycle when either:   * A live baby has been born * The couple choose not to proceed * There is clinical evidence to show that a successful outcome will not be possible   Written confirmation will be sent to the referring consultant and/or GP with a copy to the Service user detailing the reasons for the above action.  Should there be an unsuccessful treatment outcome; specialist fertility counselling will be offered at the expense of the Tertiary Provider.  Should the couple have a viable pregnancy and are requiring access to maternity services the following should occur:   * A letter confirming the pregnancy will be forwarded to the GP and referring consultant * The GP will refer the pregnant woman to the maternity services at or around 8 weeks of pregnancy * The woman should access the midwifery services between 8-10weeks |
| **6. Self-Care and Service user / Carer Information** |
| The Provider shall provide information, advice and support for self-care as set out in Section 3.1 - Service model. |

**7. Individual Funding Requests**

**All treatment must comply with the Individual Funding Request policy of the Commissioner.**

**APPENDIX 1**

**Action in the event of an IVF/ICSI treatment cycle not reaching embryo transfer**

A “non-abandoned” cycle of IVF/ICSI is one where one or more embryos resulting from treatment are transferred to the uterus. An “abandoned” cycle is one which does not reach the stage of embryo transfer.

If a cycle is abandoned further action should depended on the clinical circumstances and the reason for abandoning the cycle. If the cycle was abandoned due to predictable, non-correctable factor, further treatment should NOT be offered as it has a low likelihood of success. Where there is a non-predictable or correctable cause, further attempts should be made to achieve a completed cycle of treatment.

1. Cycle cancelled owing to poor ovarian response on maximal gonadotrophin stimulation (i.e. 450 iu FSH daily): No further treatment, as high likelihood of failure in subsequent cycles.

2. Cycle cancelled due to poor ovarian response on less than maximal

gonadotrophin stimulation: Further attempts using maximal stimulation, provided repeat Day 2 FSH is within the criteria (<8.9 iu/l)

3. Cycle cancelled due to excessive ovarian response and no eggs retrieved:

Further attempts with lower dose of gonadotrophin

4. Cycle cancelled due to excessive ovarian response, embryos created: Frozen embryo transfer.

5. Cycle cancelled due to failure of fertilisation at standard IVF: Further attempts using ICSI

6. Cycle cancelled due to failure of fertilisation using ICSI: No further treatment.

7. Cycle cancelled due to incident clinical factor coming to light during treatment (e.g. hydrosalpinx or endometrioma): Further attempts after correcting the abnormality.

8. “Exceptional” reasons (e.g. death in family): individualise on a case by case basis.

**Categories of abandoned cycles**: Abandoned cycles fall into three categories.

1. Abandoned cycles before attempted egg retrieval:

2. Abandoned cycles after unsuccessful egg retrieval attempt:

3. Abandoned cycles after successful egg retrieval (+/-embryo creation)

An NHS funded cycle of IVF/ICSI treatment is considered to have commenced once ovarian stimulation drugs have been administered.