

Treatment of Infertility Commissioning Policy

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NAME/COMMITTEE	DATE	VERSION
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DOCUMENT STATUS

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1.0 COMMISSIONING POLICY

The Treatment of Infertility Commissioning Policy has been developed to aid clinicians and patients requesting infertility treatment. The pro-forma should be completed by the GP in conjunction with the policy and as part of the medical consultation with both partners present.

Requests for Infertility Treatment are processed by Arden & Greater East Midlands Commissioning Support Unit (AGEM CSU) on behalf of Dudley Clinical Commissioning Group (CCG).

We would politely request that all infertility requests are fully considered against the current commissioning policy criteria prior to submission to AGEM CSU. This will avoid falsely raising patient expectations, unnecessary delay and disappointment of the decision (should this be to refuse treatment) and reduce unnecessary administration undertaken by the GP Practice, AGEM CSU and Dudley CCG.

Unfortunately, if treatment is refused due to the couple not meeting the criteria they are unable to appeal against the decision as there is a Commissioning Policy which has been consulted upon, approved and ratified by Dudley CCG. Patients may wish to put any comments concerning the policy in writing to Dudley CCG. These will be considered at the point of review.

Infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology. The treatment of infertility is to assist a couple in conception where such difficulties have been identified. Difficulties in the ability to maintain a pregnancy to full term are outside the scope of the treatment of infertility policy.

2.0 RANGE OF TREATMENTS INCLUDED IN THIS POLICY

Provided that the couple meet the criteria outlined within this policy Dudley CCG will fund one treatment unit of assisted conception per couple, this allows for increased access to NHS treatment and ensures that couples are treated in a timely manner.

Treatments include: in vitro fertilisation (IVF), intra cytoplasmic sperm injection (ICSI) intrauterine insemination (IUI) and egg donation. For explanation of medical terms used throughout this document see Appendix 3.

Eligible couples will be funded for one treatment unit which will comprise of:

- 1 cycle of In Vitro Fertilisation (IVF)
OR
- 1 cycle of Intra-Cytoplasmic Sperm Injection (ICSI).
OR
- 1 cycle of stimulated Intrauterine Insemination (IUI)

A cycle will consist of ovulation induction, egg retrieval, fertilisation and embryo transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.

Dudley CCG will fund the cryopreservation and storage of any suitable surplus embryos following a completed NHS funded cycle for a period of 12 months in line with Human Fertilisation and Embryology Authority (HFEA) guidelines. Following this period, the women/couple may self-fund continued storage.

Please note Dudley CCG will fund one fresh cycle, however, funding for a single frozen embryo transfer (FET) will not be met, therefore, the costs associated with FET, must be met by the couple.

Treatment options will depend on diagnosis and clinical appropriateness.

Couples should have been informed of and attempted to address frequency and timing of sexual intercourse, alcohol consumption, body weight, occupation, prescribed medication and cessation of recreational drug use.

Please note if a patient receives NHS funding for infertility treatment that results in a pregnancy, but the patient subsequently miscarries, unfortunately, no further NHS funding is available as the patient would not meet the policy on the grounds that they had previously received one cycle of treatment funded by the NHS.

3.0 PATIENT ELIGIBILITY CRITERIA

3.1 Age of Female Partner

Definition: 1 cycle of stimulated infertility treatment will be provided to couples in which the woman is aged 23-39 years, i.e. up to and including their 39th birthday, who have an identified cause of their fertility problems or who have infertility of at least 2 years' duration.

Referrals to Dudley CCG via AGEM CSU should be made by the women's 39th birthday to ensure that treatment can take place by the woman's 40th birthday. Referrals after this time will not be considered.

Reason: (Biological) Normal fertility declines with advancing age, most markedly from the late 30s onwards in women.

Exceptions: There are certain circumstances where it would not be productive for the patient to wait until they are 23 to begin treatment. In these cases treatment can commence at an earlier age as defined below:

- Cancer patients. This is to enable the removal of eggs/sperm from cancer patients prior to starting treatment. There will be no minimum age for these patients.
- Other exceptional cases will be considered by Dudley CCG at the Individual Funding Request (IFR) Screening or Full Panel if required.

3.2 Age of Male Partner

Definition: The age of the male partner at the time of treatment must be under 55 years of age.

Reason: (Biological) HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor's age on assisted conception success is considered on a case by case basis.

There is limited evidence that infertility treatment success decreases in men over the age of 40. Men aged over 40 are half as likely to conceive with infertility treatment compared to 30 year old men when their female partner is aged 35-39 years (de La Rochebrochard et al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998)

In light of some evidence that male age does impact on infertility, and may have an impact on infertility treatment outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

3.3 Male & Female Weight (BMI = Body Mass Index)

Definition: Treatment will not be provided for any woman with a Body Mass Index <19 or >30. Treatment will not be provided for any male with a Body Mass Index or >30.

Reason: (Biological) Underweight women (BMI<19) often have irregular cycles and may have a reduction in fertility as a result of ovulatory dysfunction. Significantly overweight women may frequently have ovulatory problems and may experience reduced fertility. Weight gain or reduction may spontaneously effect a cure.

Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.

Please note the height, weight and BMI of both partners **must** be included in the application. Dudley CCG is only able to offer treatment to those couples where the female partner has a BMI of above 19 and both partners have a BMI below 30. If the BMI is found to be below for a female or above the recommended range of either or both partner, funding will be automatically withdrawn until all of the criteria are met.

3.4 Duration of Fertility Problems

Definition: 2 years minimum unless infertility is absolute

Reason: (Biological) Some patients with unexplained infertility may be individuals whose fertility falls at the lower end of the normal spectrum and who will conceive spontaneously given time. In order to eliminate unnecessary treatment in this subgroup, sufficient time should be allowed for natural conception to occur.

Infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology. The treatment of infertility is to assist a couple in conception where such difficulties have been identified. Difficulties in the ability to maintain a pregnancy to full term are outside the scope of the treatment of infertility commissioning policy.

If infertility is absolute as explained in medical circumstances patients will be approved without undergoing the 2 year waiting period.

Please note:

- Sub-fertility should include no pregnancy, including ectopic or unexplained miscarriages during the 2 year sub-fertility period with the same partner. In the event a couple experience successful conception, regardless of the outcome whilst applying or waiting for NHS funded infertility treatment, NHS funding will be withdrawn as the purpose of the funding is to conceive for those who have failed.
- Absolute infertility is indicated by azoospermia. Males with subfertile sperm counts must fulfil the 2 year criteria.
- Absolute infertility is indicated by bilateral tubal absence or blockage in females.
- It is anticipated that a couple will be living together in the United Kingdom in a stable relationship and actively trying to conceive for a minimum of 2 years before applying for infertility treatment taking into account the recommendations concerning appropriate lifestyle factors.

3.5 Living Son or Daughter

Definition: Funding will not be available to couples where either partner has an existing son or daughter (including adopted) by the current relationship or from any previous relationship even when the son or daughter are not living with the couple.

Reason: (Resource Allocation) The priority for NHS funded treatment should be to deliver care to those individuals with the greatest need, which is interpreted as those couples where neither partner has had a son or daughter.

3.6 Reversal of Sterilisation

Neither partner should have previously been sterilised.

Definition: Dudley CCG will not fund the reversal of a vasectomy or sterilisation, nor will it fund fertility treatment after voluntary sterilisation including gender reassignment.

Reason: (Resource Allocation) Sterilisation is a voluntary decision and will only have been undertaken following counselling. The counselling is based on agreement that the procedure is irreversible.

3.7 Welfare of the Child

Definition: In any circumstances where there are known adverse factors which might affect the welfare of a child who might be born, GPs are asked to declare this information so that it can be considered as part of the decision making process. Please note, should the GP indicate there are concerns regarding the welfare of the child who might be born, the request for treatment will be submitted to the Individual Funding Request Panel for a decision.

Reason: (Legal) Under the provisions of the Human Fertilisation and Embryology Act 1990, assisted conception treatment can only be provided if the centre considers the conditions concerning the welfare of the child to be satisfied. See also the Human Fertilisation & Embryology Authority (HFEA) Code of Practice (1995).

3.8 Compliance with Treatment

Definition: Any couple who are considered unlikely to accept or comply with the demands of adhering to a treatment plan should, ideally, not be referred. Consideration should also be given to a woman's willingness to adopt healthier lifestyles during pregnancy.

Reason: (Social and Resource Allocation) Frequent, multiple visits to a clinic are required over the cycle of treatment. The treatment requires daily injections (often administered by the patient) and frequent monitoring. If there are concerns that a couple are unable to make a commitment to this it is best that they postpone starting treatment until they are able to, so as to prevent the commitment of scarce resources.

3.9 Smoking

Definition: The expectation is that couples accepted for treatment would be non-smoking and have not smoked for at least a year.

Reason: Maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including in vitro fertilization treatment. Smoking during the antenatal period leads to increased risk of adverse pregnancy outcomes. Minimizing

exposure to second hand smoke will ensure a healthy start to life to any child/children born as a result of assisted conception.

3.10 Drugs and Alcohol

Couples will be asked to give an assurance, before being added to the list that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs or undertaking treatment for drug addiction. Any evidence to the contrary will result in removal from the list.

The expectation is that couples accepted for treatment would be not using recreational drugs or medication for drug addiction (e.g methadone) for a minimum of 12 months.

3.11 Same Sex Couples

Applications will be considered for sub-fertility treatment for same-sex couples as long as there is proven sub-fertility. Infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a HFEA registered clinic over a minimum period of 2 years, in the absence of any known medical cause of infertility.

In circumstances in which those in a same-sex relationship are eligible for sub-fertility treatments, the other criteria for eligibility to sub-fertility treatments will apply as well.

In the case of same-sex couples in which only one partner is sub-fertile, clinicians should discuss the possibility of the other partner becoming the biological partner before carrying out interventions involving the sub-fertile partner.

NHS Funding will not be available for access to insemination facilities for fertile women who are not in a relationship.

3.12 Donor Egg

This will only be funded for women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

Please see separate policy for the Cryopreservation of Sperm and Eggs prior to Chemotherapy or Treatment for Malignancy.

3.13 Donor Sperm

This will only be funded where the male has azoospermia or severe oligospermia or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

Dudley CCG will pay for Donor Sperm from the 'Sperm bank' where couples meet the infertility criteria.

Dudley CCG will not pay for couples choosing to use a known sperm donor unless they can demonstrate that this is the last available option, e.g. no suitable sperm donors available via the sperm bank within 6 – 12 months for a specific minority group.

Please see separate policy for the Cryopreservation of Sperm and Eggs prior to Chemotherapy or Treatment for Malignancy.

3.14 Sperm Storage (prior to Chemotherapy or Treatment for Malignancy)

Patients undergoing chemotherapy and radiotherapy will be eligible for sperm storage.

Storage of sperm if agreed for will be funded by Dudley CCG for up to 5 years and can be up to 10 years if clinically indicated with doctors consent.

Dudley CCG will only pay for sperm storage while the patient is still eligible as part of a couple undergoing treatment under our policy e.g. once the female reaches the maximum age of 39. Dudley CCG will cease funding for sperm storage where applicable. In the event of a patient's death, the provider will follow HFEA procedures regarding the destruction of sperm and Dudley CCG will cease to fund the sperm storage costs associated. (The patient / family may choose to extend the period of sperm storage and treatment and will therefore be charged directly from the provider).

Please note that committing to sperm freezing, Dudley CCG is not committing to fund fertility treatment and patients must meet the infertility criteria.

Please see separate policy for the Cryopreservation of Sperm and Eggs prior to Chemotherapy or Treatment for Malignancy.

3.15 Surrogacy

Dudley CCG does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

4.0 CO-FUNDING – THE PRACTICE OF SUPPORTING PRIVATE PATIENTS USING NHS FUNDING IS NOT SUPPORTED.

This is in line with Department of Health guidance as reiterated in the National Plan.

The NHS is funded out of public expenditure, primarily by taxation. This is a fair and efficient means for raising funds for healthcare services. Individuals will remain free to spend their own money as they see fit, but public funds will be devoted solely to NHS patients, and not be used to subsidise individuals' privately funded healthcare.

Please note:

Dudley CCG does not support the cost of fertility drugs for patients who do not meet the criteria outlined in this policy.

5.0 AN INITIAL ASSESSMENT OF THE COUPLE'S COMPLIANCE WITH THE ELIGIBILITY CRITERIA WILL BE CARRIED OUT BY THE COUPLE'S GP AND THE PROVIDER CLINIC

If the couple meet all the criteria and wish to proceed with treatment the GP will be required to complete the form 'Individual Treatment Request – Treatment for Infertility (Appendix 1) during the consultation and submit to AGEM CSU on behalf of Dudley CCG for consideration.

Please attach all relevant clinical letters and reports. If infertility is absolute, e.g azoospermia or bilateral tubal absence or blockage, written evidence/report is required with application.

Patients with subfertility will be required to meet the 2 year waiting period.

Patients who may require psychosexual counselling will still need to commence infertility treatment before the female partner reaches her 39th birthday.

After checking that all criteria are met the referral will be forwarded to Birmingham Women's Fertility Clinic in the context of the resources available. If the completed form indicates that the couple does not meet the criteria the request will be referred back to the GP

If exceptional circumstances have been indicated by the GP, the request maybe forwarded to Individual Funding Request Screening or Full Panel for consideration (See flow chart in Appendix 2).

Both members of the couple should be registered with a Dudley responsible General Practitioner.

5.1 Mechanism of Funding

- Dudley CCG identifies an annual budget for this service and the number of people going forward will be contained within that amount.
- This treatment is only available to couples where **both** partners are registered with a Dudley GP. Please note, if a partner is registered with a different Dudley GP, AGEM CSU will contact them directly to obtain the clinical details of the partner required to process the application as a couple on behalf of Dudley CCG.
- Couples who are accepted for NHS funded infertility-treatment will receive all their care at a provider approved by Dudley CCG, including the prescribing and dispensing of their drugs. This ensures:
 - Equity of access to treatment for all women who meet eligibility criteria.
 - Continuity of expert clinical care.
 - Cost efficiency (large centres are likely to be able to negotiate discounts on the costs of the drugs)
- Under the terms of this policy GPs should NOT prescribe drugs on the NHS for any of their patients. When patients are accepted on to the NHS programme, their drug costs will be met by the programme. This policy empowers the GP to decline a request for a prescription. GPs are not in breach of their terms and conditions of service if they decline to prescribe.
- Once a patient is pregnant, funding of drugs to maintain the pregnancy should be undertaken by the Specialist or GP.
- Should a patient conceive naturally and does not require funding from Dudley CCG, funding is automatically withdrawn.

PLEASE NOTE

Birmingham Women's Fertility Centre are best placed to advise patients through their fertility investigations or treatments and provide all the necessary information and advice to help them make decisions that optimise their chances of conceiving.

Dudley CCG take no responsibility for the course of treatment advised by the providers i.e. ICSI or IVF or IUI and therefore should the recommended course of treatment not be successful, Dudley CCG will not fund a second treatment. A couple is entitled to one treatment unit as outlined in section 1 of this policy.

DUDLEY CCG

**INDIVIDUAL TREATMENT REQUEST
TREATMENT FOR INFERTILITY**

DUDLEY CCG recommends treatment for infertility as an option for couples providing that **all** the criteria listed below have been met. AGEM CSU on behalf of Dudley CCG will then give full consideration to your request for funding. This form should be completed as part of the medical consultation **by the GP** with reference to the Commissioning Policy for the Treatment for Infertility with both partners present. **Please note: GP, Patient & Partner Signatures required with signed declarations.**

Patient Name**Date of Birth**.....

NHS No

Address.....

.....

Patients GP.....

Patients Signature**Date**

Patients Partners Name**Date of Birth**.....

NHS No

Address.....

.....

Patients Partner GP.....

Patients Partner Signature**Date**

1. Is the woman between the age of 23 – 39? **Yes** **No**

Please note referral must be 12 months prior to woman's 40th birthday to allow for clinic time.

If the answer is no, funding will be refused

2. Is the man under 55 years of age **Yes** **No**

If the answer is no, funding will be refused

3. Does the female have a BMI between 19 and 30?
 Please state the patient's height, weight and current BMI.

Height	Weight	BMI	Yes	No
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>

Please note if BMI is not confirmed, the request cannot be considered. If BMI is below 19 or above 30, treatment will be refused.

4. Does the male have a BMI under 30?
 Please state the patient's height, weight and current BMI.

Height	Weight	BMI	Yes	No
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>

Please note if BMI is not confirmed, the request cannot be considered. If BMI is above 30, treatment will be refused.

5. Has the duration of fertility problems been for a minimum of 2 years with the current partner named in this application?
 Any pregnancies, including ectopic or unexplained miscarriages during the 2 year subfertility period will be taken as evidence of fertility.

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

6. Does the couple have an existing son or daughter (including adopted) by the current or any previous relationship?
 If yes, treatment will be refused.

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

7. Has either partner been sterilised?
 If yes, treatment will be refused.

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

8. Are you aware of any adverse factors which might affect the welfare of a child who might be born?
 Please note, if the answer is yes to this question, the request will be considered at the IFR Panel.

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

9. In your view would the couple be likely to comply with the demands of adhering to the treatment plan?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

10. In your view would the couple be willing to adopt a healthy lifestyle during pregnancy? Yes No

11. Have both partners been non-smokers for at least one year? Yes No
If no, treatment will be refused.

12. Please indicate if this couple are of the same sex. Please state which sex Yes No
Male _____ Female _____
Please attach evidence of 6 self-funded IUI attempts at HFEA registered clinic over a 2 year period.

13. Is the couples intake of alcohol within the Department of Health Guidelines? Yes No
If no, treatment will be refused.

14. Is there any evidence that the couple are currently using recreational drugs or drugs prescribed for drug addiction? Yes No
If yes, treatment will be refused.

15. Have the couple been in a stable relationship for a minimum of 2 years in the United Kingdom (i.e. living together)? Yes No

16. Can you confirm both partners are registered with a Dudley responsible GP? Yes No
Please see mechanism of funding section regarding eligibility which confirms both partners must be registered with a Dudley GP. Please note, if a partner is registered with a different Dudley GP, AGEM CSU on behalf of Dudley CCG will need to obtain clinical details to process the request as a couple and therefore will contact them directly.

17. Have all appropriate clinical investigations been undertaken before submitting this request?

Yes

No

Please attach copy of all clinical letters and relevant reports in order for the request to be processed.

Please note if funding is approved, as outlined in the approval letter, copies of relevant clinical letters and tests and reports performed by providers other than Birmingham Women's Hospital will need to be forwarded to avoid duplication & avoid delay in treatment

Only patients with evidence of absolute infertility e.g azoospermia or bilateral tubal absence or blockage will not be required to fulfil the duration of the 2 year waiting period.

18. Will the patient require an interpreter once called for an appointment? Which language, please state:

Yes

No

19. Is there any additional medical information for the patient and/or partner that may be relevant to this request. Please give details below:

20. Does either partner have a genetic or long term condition that is likely to impact on a child born as a result of treatment for sub-fertility? Please give details below:

21. If you feel there are exceptional circumstances that you feel should be taken into account please give details below:

22. If there are any additional comments, please state below:

23. GP – please confirm that you have read this policy and discussed its contents with the patient.

Yes

No

This request will be considered against the criteria outlined within the Policy and you will be advised of the outcome. If you have any queries please contact the Individual Funding Request Team, Arden & GEM CSU, Kingston House, 438-450 High Street, West Bromwich, B70 9LD. Telephone: 0121 612 2841, Fax No: 0121285 5990. Email: ifr.dudley@nhs.net

If treatment is refused due to the couple not meeting the criteria, unfortunately, they are unable to appeal against the decision as the Commissioning Policy which has been consulted upon, approved and ratified by Dudley Clinical Commissioning Group (CCG). Patients may wish to put any comments concerning the policy in writing to address above. All comments received will be considered at the point of policy review.

Doctors Declaration

I declare that the information I have given on this form is correct and complete. I understand that if I provide false information, I may be liable for disciplinary, prosecution and civil recovery proceedings. I consent to the information on this form being used for the purposes of the prevention, detection and investigation of fraud.

GP Name (Please print)

SignatureDate

Practice

Patients Declaration

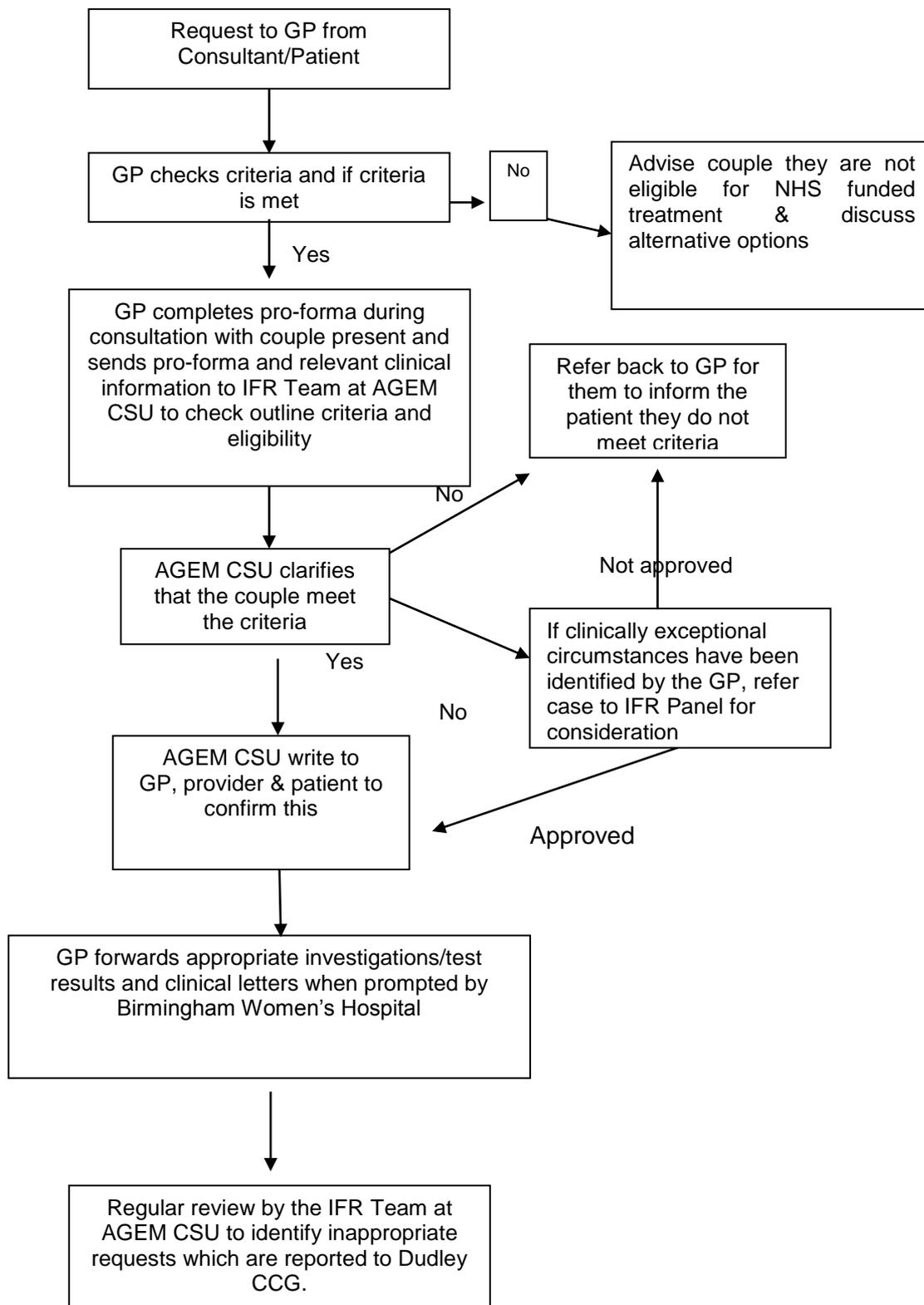
I/We declare that the information I/We have given on this form is correct and complete. I/We understand that if I/We provide false information, I/We may be liable for prosecution and civil recovery proceedings. I/We consent to the information on this form being used for the purposes of the prevention, detection and investigation of fraud. I/We understand that I/We will be entitled to one cycle of infertility treatment on the NHS and further funding is not available should the treatment not be successful. We also understand that when funding is released, if for any reason we no longer meet the criteria, i.e. smoking cessation, BMI or successful conception, regardless of the final outcome in the interim period, funding will be withdrawn as we no longer meet the criteria.

Patients SignatureDate

Partners SignatureDate

DUDLEY CCG

Process for managing requests for Treatment for Infertility



DUDLEY CCG**EXPLANATION OF MEDICAL TERMS USED IN FERTILITY TREATMENT**

ASSISTED CONCEPTION	The name for treatments that enable people to conceive by means other than sexual intercourse. Assisted reproduction techniques include intra-uterine insemination (IUI) , in vitro fertilisation (IVF) , intracytoplasmic sperm injection (ICSI) , donor insemination and egg donation .
AZOOSPERMIA *	The complete absence of sperm in male ejaculate.
BIOPSY	A procedure to take a small sample of tissue.
BODY MASS INDEX (BMI)	The measurement used to define the range of healthy weight. Your BMI is calculated by dividing your weight in kilograms by your height in metres squared (that is, your height in metres multiplied by itself).
DONOR INSEMINATION (DI) *	The introduction of donor sperm into the vagina, cervix or the womb itself.
EGG DONATION *	Donation of eggs by a fertile woman for the treatment of others or for research.
FERTILITY PROBLEM	Where no pregnancy results for a couple after 2 years of regular (at least every 2 to 3 days) unprotected sexual intercourse.
IN VITRO * FERTILISATION (IVF)	Human eggs and sperm mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into a female patient.
INSEMINATION *	The artificial placing of freshly ejaculated or frozen sperm in the female reproductive tract
INTRACYTOPLASMIC SPERM INJECTION (ICSI) *	A variation of IVF in which a single sperm is directly injected into the egg .
INTRA-UTERINE INSEMINATION (IUI) *	Insemination of sperm into the uterus of a woman.
OLIGOZOOSPERMIA	Low sperm count. Less than twenty million sperm per millilitre. Severe if less than five million sperm per millilitre.

* Taken from Glossary, Human Fertilisation & Embryology Authority (HFEA) 2005/06.