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Policy and Protocol for the management of fertility treatment in Shropshire

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Policy and Protocol for management of fertility treatment in Shropshire

1 Introduction

1.1 This policy and protocol has been developed to enhance patient care, to offset delays in the provision of fertility treatment and to support the move towards providing innovative schemes for the delivery of the best possible care within resources available through the Local Delivery Plan (LDP). It will be reviewed annually.

1.2 Shropshire Clinical Commissioning Group has reviewed their approach to infertility prevention and treatment with regard to the guidelines published by the National Institute for Health &Clinical Excellence (NIHCE) and the Royal College of Obstetricians and Gynaecologists, partly in response to the recent campaign by local and national infertility support groups to increase access to infertility treatment. Full implementation of the NIHCE clinical guideline has not been in Shropshire CCG due to budget allocation.

2 Background

2.1 3 tiers of fertility treatment services are provided for Shropshire:

- Tier 1 Primary Care - provided by General Practitioners under guidelines issued by the Shropshire and Mid-Wales Fertility Centre. General Practitioners and their teams will usually offer preliminary counselling and pre-conceptual advice, and often carry out hormonal assessments and book semen assessments. The assessment and investigations are completed after referral to the next tier if appropriate.

- Tier 2 Secondary Specialist Care – provided by the Shropshire and Mid-Wales Fertility Centre situated at the Royal Shrewsbury Hospital. The Fertility Centre offers specialist investigations, drug treatment and monitoring at a higher level than in primary care. Treatments include ovulation induction, gonadotrophins and intra-uterine insemination (IUI).

- Tier 3 Tertiary Specialist Care - provided by the Shropshire and Mid-Wales Fertility Centre. The Shropshire and Mid-Wales Fertility Centre is licensed, to perform IUI, in vitro fertilisation (IVF), intra-cytoplasmic sperm injection (ICSI), embryo freezing, sperm freezing, egg freezing, egg donation, egg sharing and donor sperm IUI. All investigations, preparations and treatments are performed at the Centre.

2.2 This policy and protocol provides for secondary and tertiary services only and work continues to ensure that community and primary care services are considered in the patient care pathway.

3 Legal Background

The National Institute for Health and Clinical Excellence (NIHCE) Clinical Guidelines for the Investigation and Treatment of Infertility

3.1 NIHCE published extensive guidance in February 2004 for the management and treatment of the infertile couple. This guidance supersedes that which had been published by the Royal College of Obstetricians and Gynaecologists (RCOG) between 1998 and 2000.

3.2 The NIHCE guideline is the most extensive and evidence-based document yet published in the field. As such it has been heavily referenced in this document and should be referred to for a more in-depth analysis and guide to treatment.

3.3 As part of its guideline NIHCE has published criteria that should be met before secondary or tertiary treatment is offered and guidance on the number and type of treatments that should be offered in specific circumstances. The criteria are outlined below for each treatment option.

4 Scope

4.1 Infertility can be defined as the failure to conceive after at least two years regular sexual intercourse. Referral after one year of failure to conceive should be considered where the woman is 35 years or older.

4.2 Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. It is estimated that infertility affects one in seven couples in the UK.

5 Objectives

5.1 This policy seeks to provide a safe, equitable and accessible fertility service to all couples where the woman has been unable to conceive, within the agreed criteria set out by Shropshire CCG.

6 Procedure

6.1 **Verification of compliance with initial criteria and assessments**

A full clinical history is taken from both partners by a Fertility Nurse including:

- Verification that all necessary access criteria are met
- Check that all previous investigations and reports have been assimilated
- Ensure that any previous records and reports are collated

Couples will then be referred into the Fertility Clinic

6.2 Diagnosis and treatment of male partners

- Routine diagnostic analysis of semen, blood group & rhesus status, HIV/ hepatitis B & C will be undertaken
- General dietary and lifestyle advice is given
- Semen testing may be repeated

Treatment for male infertility is dependant on cause.

First stage treatment

- Intra-Uterine Insemination (IUI) can be used to treat moderate sperm disorders

Second stage treatment

- Donor Insemination (DIUI) can be used where the male partner has severe sperm disorders or complete absence of sperm,

- There will also be a small demand for donor insemination by couples in whom the male partner is HIV positive.

Treatment for severe male factor infertility

- Intra-Cytoplasmic Sperm Injection (ICSI). ICSI involves the selection of individual sperm and their injection into the egg.

- ICSI can also be used in cases of azoospermia (complete absence of sperm in the ejaculate)

- Sperm are recovered direct from the testicle where possible using techniques such as Percutaneous Epididymal Sperm Aspiration (PESA) and Testicular Sperm Extraction (TESE).

6.3 Diagnosis and treatment of female partners

- Routine diagnostic tests for women may include hysterosalpingogram, laparoscopy & dye test, hormone profiles, Karyotype, cystic fibrosis screen, chlamydia screen, rubella screen, blood group & Rhesus status, HIV, Hepatitis B & Hepatitis C.

- Dietary advice and exercise may be appropriate

- Counseling and reassurance at all stages of diagnosis and pre and post treatment

First stage treatment

- In the absence of tubal disease, oral Clomiphene citrate or Tamoxifen are usually prescribed for 6 months with follicular ultrasound scanning in the first cycle to reduce the risk of over stimulation.
- In cases of unexplained infertility and mild endometriosis IUI can be used as a first line of treatment.

Second stage treatment

Drug treatment of ovulatory disorders includes:-

- In-vitro fertilisation, (IVF) used to treat ovulatory failure, some cases of male factor infertility and severe tubal damage or endometriosis.

The PCT reserves the right to undertake an audit programme from time to time regarding second stage treatment.

Surgical intervention

- Surgical interventions such as ovarian drilling and adhesiolysis may also be necessary in cases of tubal disease and endometriosis in addition to the non-surgical treatment described above or independently.

- Reversal of sterilisation should remain as a low priority service to be commissioned under exceptional circumstances only.

6.4 Other Factors

This policy should be reviewed again in the light of national recommendations from NIHCE and/or the Department of Health and in light of the 18 week pathway, in January 2009.

7 Policy for accessing the Second Stage treatments of in-vitro fertilization (IVF) and intra-cytoplasmic sperm injection (ICSI).

7.1. The CCG's general position is to limit treatment to one cycle per couple. This allows for increased access to NHS treatment and ensures that couples are treated in a timely manner.

It is good practice for all general practitioners to consider the following criteria before commencing, or referring for any treatment of infertility. These are, frequency and timing of sexual intercourse, alcohol consumption, body weight, occupation, prescribed and recreational drug use.

However it is essential that these criteria are met before referral for funding for second stage treatments.

7.2. **Patient eligibility criteria**

7.2.1 Criteria for NHS funding for Assisted Conception

Definition:

A couple is defined as two individuals in a relationship of at least two years duration, which involves them being married or cohabiting with one another. Other circumstances will be considered on an individual basis.

Treatment will only be funded for a person registered on the list of NHS patients of a GP practice with which Shropshire CCG holds a contract or, where the patient is not registered with a GP practice, he or she is "usually resident" in the geographic area covered by Shropshire CCG (See Appendix 2 for definition of 'usually registered'.

Reason:

The CCGs legal responsibility for funding health interventions only covers the areas within Shropshire County and Telford and Wrekin boundaries.

Exceptions:

Any couple who have previously received one or more cycles of treatment, including privately funded treatment, even if they meet the local criteria.-

7.2.2 Age

Definition:

One cycle of stimulated IVF treatment will be provided to couples in which the woman is aged between 23 and 37.5 years at the time of treatment, who have an identified cause of their fertility problems or who have infertility of at least 2 years' duration. Consideration should be made for referral after 1 year for women aged 35 years and over, where there has been failure to conceive. Referrals into the service should be made in appropriate time to ensure that treatment can take place by the age limit

Reason:

(Biological and Social). 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 aged 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 the Individual Special Treatment Panel at the request of the applicant's GP.

- Male infertility is another indicator for treatment to commence before the individual reaches the age of 23.

7.2.3 Maternal Weight (BMI = Body Mass Index)

Definition:

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

Reason:

(Biological) Women whose BMI is < 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.

7.2.4 Duration of Sub-Fertility

Definition:

2 years minimum

Reason:

(Biological) Some patients with unexplained sub-fertility may be individuals whose fertility falls at the lower end of the normal spectrum and who will conceive spontaneously given time.

7.2.5 Previous Assisted Conception Treatment

Definition**:**

Any couple who have had:

One or more attempts at IVF

One or more attempts at ICSI

irrespective of whether these treatments were funded privately, or by the NHS, will not be eligible for further NHS funding.

Reason:

(Biological) Patients can be expected to conceive following the appropriate assisted conception technique. Failure to do so following the amounts of procedures specified above suggests that additional unidentified factors are present, which would reduce the likelihood of further similar treatments being successful.

7.2.6 Living Children

Definition:

Funding will not be available to couples who have any existing children by the present relationship or any previous relationship.

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 who have not been able to complete their primary family unit.

7.2.7 Reversal of Sterilisation:

Neither partner should have previously been sterilised.

Definition:

Neither surgery to reverse the effects of sterilisation (whether it is male or female) nor treatment to bypass the sterilisation will be eligible for NHS funding, except in exceptional circumstances.

Reason:

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

7.2.8 Welfare of the Child

Definition:

Any known adverse factors which might affect the welfare of a child born to the couple should be taken into account.

The welfare of any existing children needs to be considered. As such, the Fertility Team will make contact with the named contact below who will check the child protection register.

Shropshire - still to be confirmed.

Reason:

(Legal) Under the provisions of the Human Fertilisation and Embryology Act 1990, assisted conception treatment can only be provided if the centre considers that the conditions concerning the welfare of the child are satisfied. See also the Human Fertilisation & Embryology Authority (HFEA) Code of Practice (New edition in force July 2007).

7.2.9 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

7.2.10 Smoking

Definition**:**

Couples accepted for treatment will be non-smokers. Previous smokers should have stopped smoking for at least 4 weeks prior to referral and continue to refrain from smoking throughout the treatment process. Smokers who wish to be referred for treatment should initially be referred to help to Quit.

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.

7.3 **Co-funding – the practice of supporting private patients using NHS funding is not endorsed**.

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 of raising funds for healthcare services. Whilst individuals remain free to spend their own money as they see fit, public funds will be devoted solely to NHS patients, and not be used to subsidise individuals' privately funded healthcare.

7.4. **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.**

7.4.1 If the couple meet the criteria and wish to proceed with treatment they will be placed on the waiting list with the agreed provider in the context of the resources available.

7.4.2 If the couple do not meet the criteria, the request will be referred back to the GP for further information for clarification, or to the Individual Funding Request Panel for consideration if exceptional circumstances have been indicated by the GP.

7.5 **Mechanism of Funding**

- The CCG identifies an annual budget for this service and the number of people going forward will be constrained by that amount.

- Couples who are accepted for NHS funded IVF/ICSI treatment will receive all their care at a provider approved by the CCG, including the prescribing and dispensing of their drugs.

- This ensures:
    - Equity of access to treatment for all individuals who meet the 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)

Amendment to Policy January 2010

This policy was reviewed in 2010 and the following revision was agreed by the Board in January 2010

Shropshire Clinical Commissioning Group will fund one cycle of treatment only

1. Amendment to Policy April 2011

8.1 When eSET is implemented by the Shropshire and Mid Wales Fertility centre, Shropshire CCG will fund **one** full cycle of IVF to include the fresh cycle and any subsequent transfer of frozen embryos (FET) in women where this is felt to be clinically appropriate to reduce the risk of multiple births.

Shropshire CCG will fund the initial freezing and 1st year's storage of the embryos. Storage beyond one year is charged to the patient should they wish to keep the embryos. There is a legal maximum of 10 years storage for embryos in the UK, after this time legally they must be disposed of.

If a patient achieves a pregnancy and delivers following a 'full' IVF cycle, they are not eligible to have any frozen embryos used subsequently paid for by the NHS.

2. Amendment to Policy April 2011

Pre-Implantation Genetic Diagnosis

SCPCT & NHS Telford and Wrekin should consider each request for PGD individually through the individual funding request process.

3. Amendment to Policy April 2011

Same Sex Couples

Applications will be considered for sub-fertility treatment for same-sex couples as long as there is proven sub-fertility. In the case of same-sex couples in which only one partner is sub-fertile, clinicians should explore the possibility of the other partner becoming the genetic parent 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 partnership or are part of a same-sex partnership. In circumstances in which those in a same-sex relationship are eligible for sub-fertility treatments, all other criteria for eligibility to sub-fertility treatments will apply as well.

Adapted from NHS Dudley Commissioning policy for treatment of Infertility 2009

4. Addition to the Policy April 2011

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.

Adapted from NHS Dudley Commissioning policy for treatment of Infertility 2009

Appendix 1

Shropshire Clinical Commissioning Group's request for treatment for infertility

Shropshire Clinical Commissioning Group recommends treatment for infertility as an option for couples providing certain criteria are met. Would you confirm, by completing this proforma, that all the criteria listed below have been met in this case. This form should be completed with reference to the Commissioning Policy for the Treatment for Infertility.

Patient Details (Name, address, date of birth)
Is the woman between the age of 23 – 37.5? Yes ☐ No ☐
Does the woman have a BMI between19 and 30? Yes ☐ No ☐
Has the duration of sub fertility been for a minimum of 2 years? Yes☐ No ☐
Can you confirm that the couple have not had any previous assisted conception? Yes ☐ No ☐
Can you confirm that the couple do not have any existing children by the current relationship or any previous relationship? Yes ☐ No ☐
Can you confirm that neither partner has been sterilised Yes ☐ No ☐
Can you confirm that both partners are registered with a Shropshire responsible GP ? Yes ☐ No ☐ If only one partner is registered can you confirm that funding has been agreed for the treatment of the other partner? Yes ☐ No ☐

Have the couple been in a stable relationship for a minimum of 2 years? Yes☐ No ☐
In your view would the couple be likely to comply with the demands of adhering to the treatment plan? Yes ☐ No ☐
In your view would the woman be willing to adopt a healthy lifestyle during pregnancy? Yes ☐ No ☐
Can you confirm that both partners are non-smokers or have given up smoking for at least 4 weeks prior to referral? Yes ☐ No ☐
If you have answered No to any of the above or if you feel there are exceptional circumstances that you feel should be taken into account please give details below:

Name ……..

Signature ……..

Practice ……..

Date ……..

Appendix 2

Definition of usually resident - taken from Who pays? The responsible commissioner DH September 2007

In general, the responsible commissioner will be determined on the basis of registration with a GP practice or, where a patient is not registered, their place of residence. See paragraph 6 below.

Paragraph 6

The general principles for establishing the responsible commissioner for NHS treatment of an individual patient (as set out under regulation 3(7) of the Functions Regulations) are as follows:
• Where the patient is registered on the list of NHS patients of a General Practitioner (GP) practice, the responsible commissioner will be the CCG that holds the contract with that GP practice.
• If a patient is not registered with a GP practice, the responsible commissioner will be the CCG in whose geographic area the patient is 'usually resident'. See Annex A (below) for more details.
• If a patient is unable to give an address, the responsible commissioner will be determined in accordance with the Functions Regulations as the CCG in which he/she is present, which will usually be the CCG where the unit providing the treatment is located.

Where a GP practice has patients resident in more than one CCG area, the current rule is that the practice will be associated with the CCG in which the largest number of the persons registered with the members of the practice reside. That CCG will then exercise the relevant commissioning functions on behalf of the practice as a whole. CCGs are however able to enter into local arrangements whereby another CCG, such as the CCG in whose area the minority of practice patients reside, agrees to exercise functions on behalf of the responsible CCG.

Annex A: Defining 'usually resident'

It is important to note that the 'Usually Resident' test must only be used to establish the responsible commissioner when this cannot be established through GP practice registration
Primarily, the arbiter of the patient's residence is the patient.
1. The principle is that the patients' perception of where they are resident (either currently, or failing that, most recently) is the criterion.
2. Certain groups of patients, for example those with HIV or AIDS, may be reluctant to provide an address. It is sufficient for the purpose of establishing financial responsibility that a patient is resident in a location (or postal district) within the CCG's geographical area, without needing a precise address. Where there is any uncertainty, the provider should ask the patient where they usually live. Individuals remain free to give their perception of where they consider themselves resident. Holiday or second homes are not considered as "usual" residences.
3. Under regulation 3(8) of the Functions Regulations, if there is any doubt over an individual's district of residence, the address that they give as where they usually reside should be used. If patients consider themselves to be resident at an address, which is, for example, a hostel, then this should be accepted. If they are unable to give an address at which they consider themselves resident, then the address at which they were last resident will establish the CCG of residence.
4. Where a patient is unable to, or incapable of, giving either a current or most recent address and an address cannot be established by other means e.g. by information from the next of kin, then a patient's district should be taken as being that in which the unit providing the treatment is located.
Questions to establish an address of usual residence should include the overseas patient charge baseline question 'where have you lived for the last 12 months?' and those who have not been in

the UK for this period should be asked further questions to establish their liability for overseas patient charges.
5. Patients should not be subjected to undue scrutiny when being asked for this information, or be 'led' into giving an alternative address in order to exploit any perceived financial advantage.
6. Under regulations 3(8A) and (8B) of the Functions Regulations, special rules apply in relation to the usual residence of prisoners – see paragraphs 79-83 of the main guidance above.