

APPENDIX 8

NORCOM COMMISSIONING POLICY

North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium

NHS Eligibility Criteria for In vitro fertilisation (IVF) Intracytoplasmic sperm injection (ICSI) and Intra-uterine insemination (IUI) treatment for people with infertility in North Derbyshire, South Yorkshire and Bassetlaw Primary Care Trusts.

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Review Date: October 05

Prepared by Rotherham PCT on behalf of North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium (NORCOM)

Introduction

This paper sets out the criteria for access to NHS funded specialist fertility services for patients who are the responsibility of the 13 PCTs covered by the North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium (NORCOM).

It sets out the minimum entitlement for NHS In vitro fertilisation (IVF) Intracytoplasmic sperm injection (ICSI) and Intra-uterine insemination (IUI) across the consortium.

There are currently significant differences between the NORCOM PCTs in respect of existing specialist fertility treatment policies. Phased introduction will be required to bring all health communities up to a common policy. It is envisaged that each PCT will adopt at least the minimum eligibility criteria. It is not intended that any PCT or health community adopt a more restrictive policy than their current policy.

Initial investigation of patients is usually carried out by a network of specialist gynaecologists at District General Hospitals throughout the NORCOM area.

In any healthcare system there are limits set on what is available and on what people can expect. Primary Care Trusts (PCT's) are required to achieve financial balance; they have a complex task in balancing this with individuals' rights to health care. It is the purpose of the criteria set out here to make the limits on fertility treatment fair, clear and explicit. Nationally this is undertaken through the work of the National Institute for Clinical Excellence (NICE) and this paper reflects this. The paper should be read in conjunction with the NICE Fertility Guidance available on their web site at www.nice.org.uk/pdf/CG011niceguideline.pdf.url (for ease of reference the NICE Guidance practice algorithms are included as part of this document at **Appendix C**).

The NICE Guidance places NHS assisted fertility services firmly in the mainstream of NHS provision. Patients as a result will expect the NHS to provide this. This document includes recommendations for the first part of the phased introduction of the Guidance. Further phases of the implementation will be defined in the light of future Department of Health requirements and the prioritisation and availability of resources.

EXCEPTIONAL CIRCUMSTANCES

Each PCT in NORCOM has a procedure for dealing with patients who consider themselves exceptions to these criteria. These patients may approach their PCT or General Practitioner who will be aware of these arrangements.

Abbreviations used in the document are explained in **Appendix A**.

Definitions of technical terms are contained in **Appendix B**.

Eligibility Criteria

1. Availability of In vitro fertilisation (IVF), Intracytoplasmic sperm injection (ICSI)

Couples suffering from infertility will be eligible for IVF and ICSI. Infertility is the failure to conceive after regular unprotected sexual intercourse for 2 years. Where there is clear reproductive pathology, couples with infertility of any duration will be considered. This will include couples who cannot achieve full sexual intercourse due to disability.

To achieve full compliance with the NICE Guidance an increase in the availability of IVF and ICSI will require phased introduction.

No element of surrogacy related infertility treatment will be eligible for NHS funding.

Any cycle of infertility treatment whether self or NHS funded will be taken into account when determining NHS funding entitlement.

Initial Phase

From 1 April 2005 all women aged between 23 to 39 who meet the NORCOM eligibility criteria will be offered a minimum of one full cycle of IVF. This includes ovarian stimulation, egg recovery, embryo transfer and frozen embryo transfer if available.

Couples who have a definitively diagnosed cause of their infertility of any duration, or unexplained infertility (unexplained infertility includes mild endometriosis and mild semen abnormality) of at least three years duration, and who have a greater than 10% chance of a live birth per cycle from in vitro fertilisation treatment (that is, where the woman's age is 39 years or less) should be offered **one** complete full cycle (that is ovarian stimulation, egg recovery and embryo transfer and frozen embryo transfer).

Where frozen embryos are available they should be transferred before the next stimulated treatment cycle up to a limit of one frozen embryo transfer.

2. Existing Children

From 1 April 2005 only couples with no children (including adopted children) living with them, who fulfil all other criteria, will be eligible.

In the interests of welfare of the child where a previous child has been taken into care as a result of child protection procedures and is not living with that parent then that parent will not be eligible.

3. Female age

Assisted reproductive technology will be available to women aged 23 to 39 years at the start of a treatment cycle. A treatment cycle begins with the administration of drugs for IVF, IUI and hormone replacement treatment.

Treatment should be started no later than 12 months from the decision to offer assisted conception. Once treatment is started a woman will be entitled to one full cycle even if they reach age 40 during treatment. All treatment will cease by the woman's 42nd birthday.

4. Male age

Assisted reproductive technology will be available to men aged less than 55 years at the start of a treatment cycle.

5. Availability of Intrauterine Insemination (IUI)

Couples who fail to conceive after 2 years unprotected sexual intercourse and fulfill the eligibility criteria for IVF may be offered intrauterine insemination if clinically appropriate.

Couples will normally be offered no more than 6 IUI treatments.

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Couples who do not conceive after IUI will have a full entitlement to IVF in line with the stated eligibility criteria.

6. Obesity

Women with a body mass index of more than 29 before starting a course of IVF ICSI or IUI will not be eligible.

Women with a body mass index of more than 29 are likely to take longer to conceive.

7. Low Weight

Women with a body mass index of less than 19 before starting a course of IVF ICSI or IUI will not be eligible.

Women with a body mass index of less than 19 are less likely to conceive.

8. Donor Sperm

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

This would mean up to 4 cycles of donor insemination. In addition IUI if required and in addition IVF entitlement if required.

9. Donor Egg

This will be available to women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause before the age of 40 or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

10. Egg and Sperm Storage

Egg storage will not be carried out outside a clinical trial. Egg storage is currently experimental. Sperm will be stored according to HFEA Guidance. This includes freezing of sperm for patients undergoing chemotherapy and radiotherapy. Patients whose sperm has been frozen prior to chemotherapy or radiotherapy will be entitled to NHS funded infertility treatment provided they meet the eligibility criteria.

11. Sterilisation

Couples where one or both partners have been sterilised will not be eligible for treatment.

12. Review

These treatment criteria will be reviewed in October 2005 or in the light of any new guidance or clinical trial data whichever is the earliest.

13. Future Phasing

Further phases of the implementation of the NICE Guidance will be defined in the light of future Department of Health requirements and the prioritisation and availability of resources.

27 October 2004

Produced by Rotherham PCT on behalf of the NORCOM PCTs

Appendix A

Abbreviations used	
BMI	Body Mass Index
DI	Donor Insemination
GP	General Practitioner
HFEA	Human Fertilisation and Embryology Authority
ICSI	Intracytoplasmic sperm injection
IUI	Intra-uterine insemination
IVF	In vitro fertilisation
NICE	National Institute of Clinical Excellence
PCT	Primary Care Trust

Appendix B

Definitions

<u>Term</u>	<u>Definition</u>	3 <u>Further information</u>
BMI	The healthy weight range is based on a measurement known as the Body Mass Index (BMI) . This can be determined if you know your weight and your height. This calculated as your weight in kilograms divided by the square of your height in metres. In England, people with a body mass index between 25 and 30 are categorised as overweight, and those with an index above 30 are categorised as obese.	BBC Healthy Living http://www.bbc.co.uk NHS Direct http://www.nhsdirect.nhs.uk
ICSI	Intra Cytoplasmic Sperm Injection (ICSI): Where a single sperm is directly injected into the egg.	Glossary, HFEA http://www.hfea.gov.uk
IUI	Intra Uterine Insemination (IUI): Insemination of sperm into the uterus of a woman.	As above
IVF	In Vitro Fertilisation (IVF): Patient's eggs and her partner's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female patient.	As above
DI	Donor Insemination (DI): The introduction of donor sperm into the vagina, the cervix or womb itself.	As above

Assessment and treatment for people with fertility problems

Initial advice for people concerned about delays in conception:

- Cumulative probability of pregnancy in general population:
 - 84% in 1st year
 - 92% in 2nd year
- Fertility declines with a woman's age
- Lifestyle advice:
 - Sexual intercourse every 2–3 days
 - ≤ 1–2 units alcohol/week for women; ≤ 3–4 units/week for men
 - Smoking cessation programme for smokers
 - Body mass index of 19–29
 - Information about prescribed, over-the-counter and recreational drugs
 - Information about occupational hazards
- Offer preconceptional advice:
 - Folic acid
 - Rubella susceptibility and cervical screening

Infertility:

Failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology

This guideline does not include the management of people who are outside this definition, such as those with sexual dysfunction, couples who are using contraception and couples outside the reproductive age range.

Early investigation if:

- History of predisposing factors (such as amenorrhoea, oligomenorrhoea, pelvic inflammatory disease or undescended testes); woman's age ≥ 35 yrs;
- People with HIV, hepatitis B and hepatitis C; prior treatment for cancer

People preparing for cancer treatment:

- Follow Royal College of Physicians and Royal College of Radiologists guidance
- Cryostorage of gametes and/or embryos

Principles of care:

- Couple-centred management
- Access to evidence-based information (verbal and written)
- Counselling from someone not directly involved in management of the couple's fertility problems
- Contact with fertility support groups
- Specialist teams

Clinical investigation of fertility problems and management strategies

For people who have not conceived after 1 year of regular unprotected sexual intercourse



