

The following recommendation was made by the Clinical Recommendations Committee (CRC), at the meeting held on 13 May 2010.

**Recommendation 08/10 The Clinical Recommendations Committee approved the implementation of the IOM Criteria for access to IVF and related Fertility Treatments.**

**The Health Services Directorate decision was to recommend to the Minister that expenditure should be capped at £40k per year, plus travel costs, with criteria as recommended by the CRC.**

Approved by the Minister on 30 June 2010.

## **IOM Criteria for Access to IVF and Related Fertility Treatments**

### **Background**

Eight four percent (84%) of couples who have no significant known causes of infertility conceive after 1 year of trying, 92% conceive after 2 years of trying and 99% conceive after 3 years. Female fertility declines significantly after 38 years of age. In the UK it is expected that about 230 new consultant referrals occur per 250,000 population per year or equivalent to 74 couples on the Isle of Man.

**Isle of Man NHS will fund up to 3 cycles of IUI or DIUI and/or one fresh cycle of IVF treatment per eligible couple plus up to one abandoned cycle or one cycle using egg donation as clinically appropriate.** One cycle of IVF treatment is defined as one fresh cycle including ovulation induction, egg retrieval, fertilisation and implantation, and includes appropriate diagnostic tests, scans and pharmacological therapy.

**All couples will be expected to have gone through the primary and secondary care pathways as defined in the NICE Clinical Practice Algorithm appropriate to them before eligibility for IVF is considered.**

<http://www.nice.org.uk/nicemedial/live.10936/29268/29268.pdf>

It is anticipated that, rarely, patients who are not eligible for treatment because they do not fulfil these criteria may, by virtue of their personal circumstances, be considered as an exceptional case for NHS funding. If this is thought to be applicable, the patients' GP or Hospital Consultant may contact the CRC Exceptional Cases Committee for consideration of funding an exceptional case.

These criteria for access will be reviewed on a regular basis.

This policy was approved by CRC in June 2010 and is effective 1<sup>st</sup> August 2010.

## CRITERIA FOR ACCESS TO Isle of Man Infertility Service.

- Only couples who qualify for NHS treatment on the Isle of Man by virtue of their residence here will be considered for funding of IVF treatment.
- Age of woman at time of cycle starting – the NHS funded cycle of IVF/ICSI should commence after the female's 23<sup>rd</sup> birthday and before the female's 38<sup>th</sup> birthday. All these cases should have been in stable partnership for at least 3 years prior to referral unless a significant primary cause of infertility is established before this period except where the female partner is older than 35 and the relationship has only been established less than 3 years.
- Age of woman at time of referral to tertiary care from secondary care – The age at referral should be after the female's 23<sup>rd</sup> birthday and before the female's 38<sup>th</sup> birthday. Women approaching the age of 38 years must be referred in time to be able to commence treatment before their 38<sup>th</sup> birthday.
- Age of Male partner – upper age limit for male partner is 55 years.
- Previous infertility treatment – Any previous NHS funded IVF/ICSI treatment for either partner will be an exclusion criterion. People who have previously self-funded treatment are eligible for one NHS-funded cycle as long as they have not already received more than 2 self-funded cycles.
- Egg donation – IVF using donated eggs from UK clinics licensed by the HFEA will be funded.
- In circumstances where women opt to have an elective single embryo transfer with freezing of remaining good quality embryos and the initial fresh cycle does **not** result in a live birth, the IOM NHS **will** also fund **one** frozen embryo transfer cycle so these embryos can be replaced. If further embryos remain in storage after this then the continued storage costs and the cost of any further replacement will become the responsibility of the couple.
- In circumstances where ovarian overstimulation occurs and the decision to freeze all embryos is made because of the risk of ovarian hyperstimulation syndrome, the Isle of Man NHS **will** fund the freezing and initial storage of the embryos. The IOM NHS will also fund **one** frozen embryo transfer cycle so these embryos can be replaced. If further embryos remain in storage after this then the continued storage costs and cost of any further replacement will become the responsibility of the couple.

- If two embryos are transferred in an NHS-funded fresh cycle of IVF and there are still sufficient good quality remaining embryos suitable for freezing the Isle of Man **will not** fund the cost of freezing, storage or subsequent replacement of such embryos. Thus, if a couple elects to have spare embryos stored in such circumstances then they must pay for this service themselves.
- In vitro maturation – IVM will not be funded, due to limited evidence of effectiveness.
- Gamete storage – Sperm storage will be funded for post-pubertal males under the age of 55 years who are about to undergo medical treatment which is likely to result in long-term subfertility. Subsequent assisted conceptions procedures using the sperm will not be funded unless the other eligibility criteria are met.
- Oocyte (egg) preservation and ovarian tissue preservation are still experimental treatments, and will not be funded. However, the evidence will be kept under review.
- Specific diagnosed causes of infertility – Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception or couples who have significant problems which will make the possibility of a natural conception very unlikely, and who meet all the other criteria, will have immediate access to IVF on reaching the eligible age range. All other couples must have infertility of at least 3 years duration.
- Blood borne viruses and sperm washing – Sperm washing for the prevention of transmission of blood borne viruses will not be funded, due to limited evidence of clinical and cost effectiveness. However, the evidence will be kept under review.
- Surgical sperm retrieval – Surgical sperm retrieval will be commissioned in appropriately selected patients, provided that the azoospermia is not the result of a sterilisation procedure or the absence of sperm production.
- Childlessness – IVF and donor insemination will only be funded if the couple does not have a living child from their relationship or from any previous relationship. This includes a child adopted (but excludes fostering) by the couple or in a previous relationship.
- Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be eligible for treatment.

- Sterilisation – Fertility treatment will not be available if the subfertility is the result of a sterilisation procedure in either partner. In addition, the surgical reversal of either male or female sterilisation will not be funded except in exceptional circumstances.
- BMI – Women must have a BMI of between 19.0 and less than 30 (for a period of 3 months or more) before receiving any treatment. They should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. GPs are encouraged to provide unambiguous and clear information about BMI criteria to infertile couples. Male partners must have a BMI less than 35.
- Smoking – Only non-smoking couples will be accepted onto the IVF treatment waiting list. (Smoking couples who have attended the local Quit4you smoking cessation programme for at least six consultations may be referred to the Exceptions committee of the CRC for a funding decision provided their GP or Consultant puts their case to this committee). They must be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. GPs are encouraged to provide unambiguous and clear information about the risks of smoking tobacco to infertile couples.
- A statement should also be issued to the couple at the time of discussing the eligibility criteria, emphasising the importance of an active, healthy lifestyle and highlighting the dangers of smoking and passive smoking, obesity, alcohol and caffeinated beverages as important causes of infertility.
- HFEA Code of Ethics – Couples not conforming to the HFEA’s Code of Ethics will be excluded from having access to IOM NHS funded assisted fertility or other treatment. This includes consideration of the ‘welfare of the child which may be born’ which may take into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.
- Donor sperm – Where the use of donor sperm is necessary and all other inclusion criteria are met, the Isle of Man will fund up to 3 cycles of donor insemination or a maximum of 3 cycles of intrauterine insemination and, if a successful pregnancy has not occurred, 1 cycle of stimulated IVF using donor sperm.
- Women in same sex couples who wish to bear children – Infertility treatment will be funded for women in same sex couples if those seeking treatment are demonstrably infertile. In the case of women in same sex couples in which only one partner is infertile, clinicians should discuss

the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner. NHS funding will not be available for access to insemination facilities. In circumstances in which women in a same sex partnership or individuals are eligible for infertility treatment, the other criteria for eligibility for infertility treatments will also apply. Women in same sex couples should have access to appropriate professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish.

**Recommend:** IVF services on the Isle of Man as **RESTRICTED PRIORITY** with funding levels to be determined by Division meeting and the Minister for DoH.

CRC  
June 2010

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