November 2019

ERY CCG COMMISSIONING STATEMENTS

East Riding of Yorkshire Clinical Commissioning Group

Patient Eligibility This policy applies to the following interventions**:**

Assisted Reproduction Techniques (ART) **OPCS Codes:** Q131, Q132, Q133, Q134, Q135, Q136, Q137, Q138, Q139, Q383	**Infertility** The care pathway for infertility problems and the access criteria for routine referral to specialist tertiary care are outlined below. In addition, NHS East Riding of Yorkshire CCG will consider, via the Individual Funding (IFR) process: • Requests from clinicians for individual fertility related treatments not explicitly including in this policy; • Requested for ART treatment for patients who fall outside the stated eligibility criteria The referring clinician must explain in fully why exceptional clinical circumstances apply. **The Care Pathway** Treatment for infertility problems may include counselling, lifestyle advice, drugs, surgery and assisted reproduction techniques such as IVF. The care pathway for infertility begins in primary care where the first stage of treatment is generally lifestyle advice to increase the chance of conception happening naturally. If this is not effective, initial assessment such as semen analysis will take place. If appropriate the couple will then be referred to secondary care services where further investigations and treatment will be carried out. This might involve surgical treatment or use of hormonal drugs to stimulate ovulation. If this is successful or inappropriate and the couple fit the eligibility criteria they will then be referred to tertiary care for assessment for assisted conception techniques such as IVF, DI, IUI and ICSI. All clinically appropriate individuals and couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. However, only couples meeting the eligibility criteria should be referred to tertiary care fertility services. **Defining infertility and access to Tertiary Fertility Services** Infertility in women of reproductive age is defined as: • The presence of know reproductive pathology OR, in the absence of any known cause of infertility: • The inability to conceive after 2 years of regular unprotected vaginal sexual intercourse, OR, if using artificial insemination (AI) (with partner or donor sperm) • Failure to conceive after 6 cycles of AI attempts OR, for same sex couples, 6 self-funded round of IUI

	Women meeting this definition will be offered further clinical assessment and investigation along with their partner (unless donor sperm has been used). However, in certain circumstances, earlier referral to Fertility Services will be offered, where: • Treatment is planned that may result in infertility (such as treatment for cancer); • The women is aged 36 years and over; • There is a known clinical cause of infertility or a history of predisposing factors for infidelity; • The person concerned about their fertility is known to have a chronic viral infection (such as hepatitis B, hepatitis C or HIV) in which case referral to a specialist tertiary centre may be required). **Eligibility criteria for assisted reproduction techniques** Eligibility criteria apply at the point patients are referred to tertiary care and apply equally to all assisted reproduction treatments whether using partner or donor sperm: • Couples must meet the definition of infertility, as described above. • To be eligible for referral to receive ART treatment, the woman must be registered with an East Riding of Yorkshire GP contracted and/or aligned to NHS East Riding of Yorkshire CCG. (Women living within the geographical boundary of East Riding but not registered with any GP should note that the care pathway for fertility treatments starts in primary care and therefore it is essential to be registered with a GP to go on to access ART.) • Neither partner should have any children (biological or adopted) from the current or any previous relationships. • This Policy uses the same age-related criteria as the access criteria for IVF, which is founded on clinical reasoning and reflects the decreasing chances of successful conception with increasing age up to 42. However, referrers should be mindful of patients' age at the point of referral and the age limit for new IVF cycles (see below). • The female patient's BMI should be between 19 and 30 prior to referral to tertiary services. Women with a higher BMI should be directed to healthy lifestyle interventions prior to referral. However, BMI's outside this range will be considered via the Individual Funding Request (IFR) process in the context of other individual factors including age. NHS East Riding of Yorkshire CCG will not commission ART for patients who are sterilised or have unsuccessfully undergone reversal of sterilisation. **Access criteria for IVF:** **Age and number of cycles:** In women aged under 40 years either with a known cause of infertility or unexplained infertility and no conception after 2 years of regular unprotected intercourse (or 12 cycles of AI, where 6 or more are by IUI)<

	NHS East Riding of Yorkshire CCG will commission 1 full cycle of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, the current full cycle will be completed. In women aged 40-42 years, either with a known cause of infertility or unexplained infertility and no conception after 2 years or regular unprotected intercourse (or 12 cycles of AI, where 6 or more are by IUI, NHS East Riding of Yorkshire CCG will commission 1 full cycle of IVF, with or without ICSI provided the following 3 criteria are fulfilled: • They have never previously had IVF treatment; • There is no evidence of low ovarian reserve; • There has been a discussion on the additional implications of IVF and pregnancy at this age. Where investigations show there is no chance or pregnancy with expectant management OR where, after assessment, IVF is considered as the only effective treatment, the woman may be referred directly to a specialist team for IVF treatment. The provider will take into account the outcome of previous IVF treatment when assessing the likely effectiveness and safety of any further IVF cycles. **Previous self-funded cycles** Any previous full IVF cycle, whether self or NHS funded, will count towards the total number of cycles offered by the NHS. The definition of a full IVF cycle is one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos. **Treatment limits** Treatment limits are per couple and per individual e.g., where a woman in a heterosexual relationship undergoes a maximum number of cycles with one partner, she is not entitled to further cycles with a different partner. Where a woman in a same sex couple undergoes the maximum number of cycles with one partner, her partner is not then also entitled to a maximum number of cycles. Intrauterine Insemination (IUI) NHS East Riding of Yorkshire CCG will commission an initial consultation to discuss the options for attempting conception in the following groups: • People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm; • People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is IHV positive; • People in same sex relationships. Where clinically appropriate in these groups (e.g., unexplained infertility after a number of AI attempts), a minimum of 6 cycles of IUI may be

	offered as an alternative to vaginal sexual intercourse, up to a total of 12 cycles, before IVF will be considered. In women over 36 years, OR where clinical investigations suggest IUI would not be considered the most effective treatment, the minimum number of IUI cycles may be reduced. **SPECIAL ART PROCEDURES;** **IVF with Intracytoplasmic Sperm Injection (ICSI)** The recognised indications for treatment by ICSI include couples where the male partner shows: • Severe deficits in semen quality; • Obstructive azoospermia; • Non-obstructive azoospermia. **<u>Donor sperm / Donor insemination</u>** Donor sperm will be funded but it will be the responsibility of the Provider to source. The use of donor insemination is considered effective in managing fertility problems in couples affected by the following conditions: • Obstructive azoospermia; • Non-obstructive azoospermia; • Severe deficits in semen quality in couples who do not wish to undergo ICSI. Donor insemination should be considered in conditions such as: • Where there is a high risk of transmitting infectious disease to the offspring or woman from the man; • Severe rhesus isoimmunisation. Couples using donor sperm should be offered IUI in preference to ICI, and where the woman is ovulating regularly they should be offered up to 6 cycles of donor insemination 9dependant on the availability of donor sperm) for conditions listed under this recommendation, without ovarian stimulation to reduce the risk of multiple pregnancy and its consequences. **Donor eggs** The use of donor oocytes will be commissioned for the following conditions: • Premature ovarian failure • Gonadal dysgenesis including Turner Syndrome; • Bilateral oophorectomy; • Ovarian failure following chemotherapy or radiotherapy; • Certain cases of IVF treatment failure. Oocyte donation will be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring. Patients eligible for treatment with donor eggs will be placed on the waiting list for treatment with donor eggs. Unfortunately, the availability

	of donor eggs is severely limited in the UK. There is therefore no guarantee that eligible patients will be able to proceed with treatment. Patients will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the eligibility criteria are still met. NHS East Riding of Yorkshire CCG will fund the additional costs associated with treatment using donor eggs but the responsibility for sourcing donor eggs will be with the Provider. **CRYOPRESERVATION** Embryo and sperm storage will be funded for patients who are undergoing NHS fertility treatment. Storage will be funded for a maximum of 3 years. Cryopreservation related to fertility preservation in patients undergoing cancer treatment is outside the scope of this Policy. Any embryo storage funded privately prior to the implantation of this policy will remain privately funded. **HIV / HEPATITIS B / HEPATITIS C:** Special procedures for treatment apply and patients may be referred to a different specialist tertiary centre. **Evidence/Rationale** In couples having unprotected regular vaginal intercourse, after 2 years the overall cumulative pregnancy rate is about 92%, leaving 8% of couples unable to conceive and where medical intervention may be possible. The main causes of infertility in the UK are (percent figures indicate approximate prevalence): • Factors in the male causing infertility (30%); • Unexplained infertility (no identified male or female cause) (25%); • Factors in the female e.g., ovulatory disorders (15%), tubal damage (15%), other factors (5%); • Problem in both partners (10%). Once a diagnosis has been established, treatment falls into 3 main types: • Medical treatment to restore fertility (for example, the use of drugs for ovulation induction); • Surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis); • Assisted reproduction techniques (ART) any treatment that provided a means of conception other than vaginal intercourse. Tertiary Fertility Services provide assisted reproduction techniques (ART): Intrauterine Insemination (IUI), Intracytoplasmic Sperm Injection (ICSI) and IVF. They may also include the provision of donor sperm and donor eggs.

Cosmetic Plastic Surgery **OPCS codes:** Not applicable	**Cosmetic Indications** When commissioning plastic surgery, NHS East Riding of Yorkshire CCG has to ensure that there is appropriate access to services for patients who are undergoing treatment for: • Trauma and surgery; acute repair and acute reconstruction • Cancer surgery and reconstruction • Burns; acute care and reconstruction NHS East Riding of Yorkshire CCG will routinely commission plastic surgery in these circumstances and patients may be referred directly to secondary care. Cosmetic surgical procedures for the correction of changes associated with age, pregnancy, weight or because of unhappiness with body image are of low priority. These will not be routinely commissioned from or performed by secondary / tertiary services in Plastic Surgery, Dermatology, General Surgery, Ophthalmology or any other specialty or primary care based Minor Surgery Services, unless exceptional clinical need can be demonstrated and prior approval given by the IFR. A patient may be considered to be exceptional to the general policy if both the following apply: • He / she is different to the general population of patients who would normally be refused the healthcare intervention • There are good grounds to believe that the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition Only evidence of clinical need will be considered. Factors such as gender, ethnicity, age, lifestyle or other social factors such as employment or parenthood will not be considered. **Evidence/Rationale** It is the responsibility of NHS East Riding of Yorkshire CCG to commission the most clinically and cost effective treatments for its local population within the resources available to it. Treatments which are primarily cosmetic in nature are, therefore, considered a low priority.
Cyclone Plus Therapy **OPCS codes:** Not applicable	**For a number of neurological conditions, including Spinal Cord injury, Multiple Sclerosis, Cerebral Palsy, Acute Brain Injury and Stroke** NHS East Riding of Yorkshire CCG does not commission referral to Cyclone Plus Therapy nor any of the treatments that are offered through this provision.

	Evidence/Rationale Cyclone Plus offers 3 different FES devices, all with the capacity to stimulate up to 16 muscle groups during a session: the RT200, the RT300 and the RT600. There is limited external peer reviewed published research evidence available to support the use of these devices. (Ref 2,3,4)

Hip Replacement Surgery (THR) **OPCS Codes:** Primary Hip replacement W371 Cement W381 Uncemented W391 Unspecified	The Commissioner **WILL SUPPORT** joint replacement surgery for patients where there is evidence to suggest that: a. Symptoms have failed to respond to conservative treatments undertaken within primary care including exercise and activity engagement, weight loss where appropriate, up to Step 3 Analgesia, and physiotherapy (in line with the Royal College of Surgeon's guidance, each treatment should be attempted for 12 weeks to determine efficacy) b. The patient has been assessed, has no obvious contraindications to surgery and is ready and willing to undergo treatment if required. Patients with BMI>=30 should be referred for weight management interventions alongside their referral.

Irrigation of external auditory canal for removal of wax Primary procedure code D071	**Background** **Patients who are suspected of suffering from malignancy should be referred under the two week cancer pathway which does not require prior approval.** Patients presenting in primary care with problems with ear wax is a common issue for healthcare providers with around 4 million ears per annum being irrigated (Guest et al, 2004). Ear wax may be wet or dry and is a normal physiological substance that protects the ear canal. It has several functions including aiding removal of keratin from the ear canal (earwax naturally migrates out of the ear, aided by the movement of the jaw). It cleans, lubricates, and protects the lining of the ear canal, trapping dirt and repelling water. Although wax frequently obscures the view of the tympanic membrane it does not usually cause hearing impairment. It is only when the wax is impacted into the deeper canal against the tympanic membrane (often caused by attempts to clean out the ear with a cotton bud, or by the repeated insertion of a hearing aid mould) that it is likely to cause a hearing impairment. The vast majority of patients presenting with problems to primary care will be managed in primary care with advice or irrigation. **Commissioning Position** Prior to referral to acute care for an ear problem, evidence must be collated to show the treatments received in primary care. A referral for ear wax removal to acute care is only commissioned for patients meeting at least one of the criteria set out below: • The patient has previously undergone ear surgery (other than grommets insertion that have been extruded for at least 18 months); • Has a recent history of Otalgia and /or Otitis media middle ear infection (in the past 6 weeks); • Recurrent Acute Otitis Externa which is not responding to primary care treatment; • Has a current perforation or history of ear discharge in the past 12 months; • Has had previous complications following ear irrigation including perforation of the ear drum, severe pain, deafness, or vertigo; • Two attempts at irrigation of the ear canal following intensive use of ear wax softeners in primary care are unsuccessful; • Cleft palate, whether repaired or not. • Painful or acute otitis externa with an oedematous ear canal and painful pinna. • Presence of a foreign body in the ear.

	• Hearing in only one ear if it is the ear to be treated, as there is a remote chance that irrigation could cause permanent deafness. • Confusion or agitation, as they may be unable to sit still. • Inability to cooperate, for example young children and some people with learning difficulties. Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Individual cases will be reviewed at the Commissioner's Individual Funding Request Panel upon receipt of a completed request form from the patient's GP, Consultant or Clinician. Requests cannot be considered from patients personally. **Evidence/Rationale** NICE Clinical Knowledge Summary - http://cks.nice.org.uk/earwax Rotherham Primary Ear Care & Audiology Services - www.earcarecentre.com Guest,J.F., Greener,M.J., Robinson,A.C. and Smith,A.F. (2004) Impacted cerumen: composition, production, epidemiology and management. QJM. 97(8), 477-488.
Knee Replacement Surgery (TKR) **OPCS codes:** Primary Knee Replacement W401 Cemented W411 Uncemented W421 Unspecified	The Commissioner **WILL SUPPORT** joint replacement surgery for patients where there is evidence to suggest that: a. Symptoms, including pain and disability sufficiently significant to interfere with a patients daily life, have failed to respond to conservative treatments undertaken within primary care including exercise and activity engagement, weight loss where appropriate, up to Step 3 Analgesia and physiotherapy (in line with the Royal College of Surgeon's guidance, each treatment should be attempted for 12 weeks to determine efficacy). b. The patient has been assessed, has no obvious contraindications to surgery and is ready and willing to undergo treatment if required. Patients with BMI>=30 should be referred for weight management interventions alongside their referral.

Spinal Fusion Surgery **OPCS Codes:** V371-379 V381-389	The Commissioner **WILL SUPPORT** funded treatment if there is clear evidence that the patient is experiencing chronic back pain and there is evidence of: a. Clear cut root compression and/or b. Spinal stenosis and/or c. Chronic instability Spinal fusion for disc conditions will be supported provided there is clear evidence that the patient has proven degenerative back pain despite active engagement in the pain management programme for a period of more than two years. **NO OTHER SURGERY IS ROUTINELY FUNDED.**

Therapeutic Ultrasound in Physiotherapy **OPCS Code:** **not applicable**	The Commissioner **DOES NOT SUPPORT** funding of this treatment due to lack of evidence of clinical efficacy.