NHS Hull Clinical Commissioning Group

General Commissioning Policy

Treatment	Diagnostic Cystoscopy (adults)
For the treatment of	Haematuria (presence of red blood cells in urine)
Background	Cystoscopy is commissioned in line with the recommendations in the NICE clinical guideline on Referral for Suspected Cancer: Recognition and Referral (NG12 June 2015) . The Hull and East Yorkshire Hospital Urology Directorate has developed a local pathway which also is in line with the Joint British Association of Urological Surgeons (BAUS) and Renal Association Guidelines (2009).
Commissioning position	A cystoscopy involves looking inside the bladder and/or urethra with an instrument called an endoscope, usually carried out under local anaesthesia. Cystoscopy is commissioned in line with the recommendations in the NICE clinical guideline on Referral for Suspected Cancer: Recognition and Referral (NG12) , as outlined below. **General recommendations** A patient who presents with symptoms or signs suggestive of urological cancer should be referred to the Urology MDT. **Specific recommendations** NB. Primary care referral to a consultant urologist is for initial assessment of symptoms only, and referrals should not be made without following the threshold criteria below. Based on the findings the consultant may recommend a cystoscopy as part of a one stop haematuria clinic. Referral letters should contain a clear indication of the grounds for referral against the threshold criteria any relevant medical history and current medication. **Referral to Secondary care for Haematuria, suspected bladder or renal cancer** - For over 45 with unexplained visible haematuria - Over 60 with unexplained non visible haematuria GP to fax to haematuria clinic within Urology Department **Other Haematuria** Referral to secondary care for patient with - <45 with unexplained visible haematuria - 40 – 60 with unexplained non-visible haematuria (2 of 3 dipsticks positive) NB: Not 2 Week wait - To include whether symptomatic or asymptomatic and smoking **Recurrent Haematuria** Defined as patients who have previously been investigated with imaging and cystoscopy **Referral to secondary care:** For any patient >45 with recurrent visible haematuria – refer on the 2 week wait referral For recurrent non – visible haematuria refer for Urology clinic appointment

Effective from	February 2016
Summary of evidence / rationale	Recommendations are consistent with the existing evidence based NICE guideline (Ref 1) and also the Joint British Association of Urological Surgeons (BAUS) and Renal Association Guidelines (2009) (Ref 2).
Date	February 2016
Review Date	June 2019
Contact for this policy	Karen Billany, Head of Acute Care, NHS Hull Clinical Commissioning Group. karen.billany@nhs.net

Definitions:

Microscopic haematuria: (also known as Non-Visible Haematuria (NVH), invisible or dipstick positive haematuria [ie. 1+ on dipstick urinalysis]) may be symptomatic or asymptomatic. Symptoms may include: lower urinary tract symptoms (LUTS); hesitancy; frequency; dysuria; loin pain or supra-pubic pain.

Macroscopic haematuria: otherwise referred to as Visible Haematuria (VH), gross or frank haematuria. Urine is coloured pink or red.

References:

1. NG 12 NICE Guideline for Suspected Cancer: Recognition and Referral June 2015 http://www.nice.org.uk/guidance/ng12

2. Joint British Association of Urological Surgeons (BAUS) and Renal Association Guidelines (2009).

Intervention	**Gamete Harvesting and Storage**
For the treatment of	Harvesting and Storage of viable gametes in patients undergoing NHS funded medical treatment (s) that cause infertility
Commissioning Position	Humber CCGs agree to fund the harvesting and subsequent storage (cryopreservation) of viable gametes, for an initial period of 10 years, for patients undergoing NHS funded medical treatment that may leave them infertile. If after the initial 10 year period storage is still required, an IFR application should be made as an exceptional request, provided the patient wishes to keep their sample for potential future use. Each case will be considered on its own merit and in line with the HFEA legislation. Approval for harvesting and cryopreservation does not guarantee future funding of assisted conception or fertility treatment – in this instance the specific CCG policy for assisted conception should be applied. Prior to fertility preservation, the secondary care clinician at the organisation providing the fertility service must confirm: • That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes) • That the impact of the treatment on fertility has been discussed with the patient • That the patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years • That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment **Cryopreservation in males** In general, it is recommended that at least two semen samples are collected over a period of one week. The CCGs will commission a maximum of three samples of semen; this is considered sufficient to provide future fertility. Testicular tissue freezing is considered experimental and will not be funded. Note: testicular sperm retrieval is commissioned by NHS England and not by the CCGs. **Cryopreservation in Females** The CCG will normally fund one cycle of egg retrieval, with or without fertilisation. If fewer than 10 eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered. Ovarian tissue storage is considered experimental and will not be funded. **Age** There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.

	Previous sterilisation Gamete retrieval and cryopreservation will not be funded where the patient has previously been sterilised. **NHS Funded Assisted Conception** Access to NHS funded harvesting and cryopreservation will not be affected by previous attempts at assisted conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the CCG's IVF policy at the time of any funding application. **Expectations of Providers** Cryopreservation of gametes or embryos must meet the current legislative standards, i.e. under Human Embryo and Fertility Act 1990. The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The patient and their partner must be made aware of the legal position on embryo ownership should one partner remove consent to their ongoing storage or use. The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful. Patients will need to provide annual consent for continued storage. The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent and has outlined the purposes for which they can be used. **Expectation of the Patient** The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide on-going consent may result in the destruction of stored materials.
Effective From	01/11/2020
Policy Review Date	30/09/2022

General Commissioning Policy

Treatment	Total Hip and Knee Replacement
For the treatment of	Osteoarthritis of the Hip and Knee
Background	This policy is needed in order to clarify the patient criteria which must be fulfilled in order for elective Hip and Knee Replacement procedures to be commissioned.
Commissioning position	Referral to an acute provider for consideration of hip and knee replacement surgery should only be made if specific criteria are met, as detailed at ***Appendix 3*** *Referral criteria elective Hip and Knee Replacements* for routine referral to orthopaedic services. Further information relating to *Hip and Knee replacement GP Guidance, Hip replacement Trust triage and Knee replacement Trust triage are detailed at* ***Appendix 4.*** **Hip Replacement** The most common indication for elective primary total hip replacement (THR) is degenerative arthritis (osteoarthritis) of the joint. Other indications include rheumatoid arthritis, injury, bone tumour and necrosis of the hip bone. The relevant 3-character OPCS codes6 (where used for elective primary hip replacement for osteoarthritis) include: W37 – Total prosthetic replacement of hip joint using cement W38 – Total prosthetic replacement of hip joint not using cement W39 – Other total prosthetic replacement of hip joint W93, W94, W95 - Hybrid prosthetic replacement of hip joint **Knee Replacement** The most common indication for elective total knee replacement (TKR) is degenerative arthritis (osteoarthritis) of the joint. Other indications include rheumatoid arthritis, osteonecrosis and other types of inflammatory arthritis. The relevant 3-character OPCS codes7 (where used for elective primary knee replacement for osteoarthritis) include: W40 Total prosthetic replacement of knee joint using cement W41 Total prosthetic replacement of knee joint not using cement W42 Other total prosthetic replacement of knee joint **Definitions of pain and functional limitation levels – *Appendix 1*** Smoking cessation and weight management should be considered as an integral part of appropriate clinical management prior to consideration of any elective surgery. Referral to smoking cessation and the appropriate weight management service should be completed as part of the primary care treatment for Hip and Knee conditions.

	Patients whose pain is so severe and/or mobility so compromised that they are in immediate danger of losing their independence and that joint replacement would relieve this threat, or patients in whom the destruction of their joint is of such severity that delaying surgical correction would increase the technical difficulty of the procedure The CCG recognises there will be exceptional, individual or clinical circumstances when funding for treatments designated as low priority will be appropriate. Individual funding requests should only occur in exceptional circumstances where the patient does not meet the core criteria. In this instance the completion of an Individual Funding Request is required. All referrals to the provider should demonstrate how the patient has met the minimum referral criteria ***Appendix 3*** and the appropriate Hip or Knee proforma completed ***Appendix 2*****.** Incomplete referrals may be returned for further information. **Not routinely commissioned** – This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG. **Restricted** – This means the CCG will fund the treatment if the patient meets the stated clinical threshold for care. (Hip and Knee Policy)
	August 2016
Summary of evidence / rationale	**Hip Replacement** A review of systematic reviews and health technology assessments looking at the evidence base for clinical measurement tools to assess referral threshold for hip replacement was undertaken in 2010 by the Aggressive Research Intelligence Facility (ARIF) at the University of Birmingham. This found no systematic reviews or health technology assessments that had directly investigated clinical measurement tools to help treatment decisions regarding hip replacement. However, it identified two clinical guideline documents that gave recommendations on referral of patients for hip replacement and one systematic review that examined the effectiveness of clinical pathways in the treatment of patients with hip pathology. Of the guidelines, one was issued by the National Institute for Health and Clinical Excellence (NICE). The NICE guidelines suggested that "referral for joint replacement surgery should be considered for people with osteoarthritis who experience joint symptoms (pain, stiffness, reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment. Referral should be made before there is prolonged and established functional limitation and severe pain."

A number of CCG's in England have existing published policies on thresholds for referral of patients with hip pain due to osteoarthritis from primary care to secondary care and/or thresholds for elective primary hip replacement surgery.

A local simple literature review was carried out to explore the range of commissioning policies for total hip replacement that were in place in CCG's nationally. Further to a review of 10 commissioning policy documents found covering 27 CCG's* the following has been identified and consistent in terms of policy and approach to the commissioning of primary total hip replacement surgery.

Background

There is a national trend toward increasing demand for joint replacement surgery, with the total number of operations growing from approximately 105,000 procedures in 2005 to approximately 178,073 replacement procedures in 2012 (source: National Joint Registry)

- 90,482 knee
- 84,488 hip
- 590 ankle
- 288 elbow
- 2,225 shoulder

Total hip replacement is a common intervention carried out in the NHS. The most frequent indication for this is degenerative osteoarthritis in adults (92% in 2012 diagnosed).

Complications occur in approximately one in 100 cases for hip replacement and can be severe (including pulmonary embolism) therefore should only be considered when other treatments have failed.

Knee Replacement

Guidelines on osteoarthritis issued by the National Institute for Health and Clinical Excellence (NICE) suggest that "referral for joint replacement surgery should be considered for people with osteoarthritis who experience joint symptoms (pain, stiffness, reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment. Referral should be made before there is prolonged and established functional limitation and severe pain."

A consensus statement from the British Orthopaedic Association and the British Association for Surgery of the Knee – published in 2001, but reported to be still current – states that "severe pain and disability with accompanying radiological changes in the knee are almost always the indications for the operation, in patients where conservative treatment has failed or is futile. Occasionally there may be an indication to replace a knee because of progressive deformity and/or instability, and pain may not necessarily be the most significant factor. Where comorbidities exist, risk benefit considerations may rule out the operation in an individual patient."

	A local simple literature review was carried out to explore the range of commissioning policies for total knee replacement that were in place in CCG's nationally. Further to a review of 11 commissioning policy documents found covering 18 CCG's* the aforementioned criteria within this policy was identified and consistent in terms of policy and approach to the NHS Hull CCG commissioning of primary total knee replacement surgery. **Background** Total knee replacement can be performed for a number of conditions, but it is most often for osteoarthritis of the knee (98% in 2012 diagnosed). Osteoarthritis of the knee presents with joint pain, deformity, stiffness, a reduced range of movement and sometimes giving way. Complications occur in approximately one in 20 cases for knee replacement and can be severe (including pulmonary embolism, ligament, artery or nerve damage and knee cap becoming dislocated) therefore should only be considered when other treatments have failed. Non-surgical management includes medications for pain and inflammation, weight reduction in patients who are overweight and obese via weight management programmes, walking aids, cushion-soled footwear. GP's can inject corticosteroids into the knee joint to relieve inflammation for periods of up to 6 -12 months. If these therapies are insufficient, a partial or total knee replacement may be necessary. The usual indications for a knee replacement are pain and disability with accompanying radiological changes. Occasionally knee replacements are done to manage a progressive deformity/instability. **Referral** Prior to referral for total hip and knee replacement, non-surgical treatments should be offered for all patients and the management of any underlying medical conditions should be optimised. This includes medications for pain and inflammation, education and advice, and weight reduction in patients via weight management programmes. Referral decisions should not be made on the basis of hip radiography as this is thought to be unreliable.
Date	August 2016
Review Date	June 2019
Contact for this policy	Karen Billany, Head of Acute Care NHS Hull Clinical Commissioning Group. karen.billany@nhs.net

References:

1. **NICE Pathways:** Management of Osteoarthritis: Referral for consideration of Joint Surgery
http://pathways.nice.org.uk/pathways/osteoarthritis#path=view%3A/pathways/osteoarthritis/management-of-osteoarthritis.xml&content=view-node%3Anodes-referral-for-consideration-of-joint-surgery

2. **NICE Clinical Guideline** Osteoarthritis 177
https://www.nice.org.uk/guidance/cg177

3. **Aggressive Research Intelligence Facility (ARIF) (2010) Clinical measurement tools and referrals for hip replacement.** http://www.arif.bham.ac.uk/reports/Report-Clinical-Measurement-Tools-and-Referrals-for-Hip-Replacement-April-2010.pdf

4. **The National Collaborating Centre for Chronic Conditions** (Royal College of Physicians) / National Institute for Health and Clinical Excellence (NICE) (2008) Osteoarthritis - National clinical guideline for care and management in adults.
http://www.nice.org.uk/nicemedia/pdf/CG059FullGuideline.pdf

5. **NHS Evidence** - National Library of Guidelines. Knee replacement: a guide to good practice.
http://www.library.nhs.uk/GuidelinesFinder/ViewResource.aspx?resID

Appendix 1

Definitions of pain and functional limitation levels

Pain Level

Mild	Pain interferes minimally on an intermittent basis with usual daily activities Not related to rest or sleep Pain controlled by one or more of the following; NSAIDs with no or tolerable side effects, aspirin at regular doses, paracetamol
Moderate	Pain occurs daily with movement and interferes with usual daily activities. Vigorous activities cannot be performed Not related to rest or sleep Pain controlled by one or more of the following; NSAIDs with no or tolerable side effects, aspirin at regular doses, paracetamol
Severe	Pain is constant and interferes with most activities of daily living Pain at rest or interferes with sleep Pain not controlled, even by narcotic analgesics

Functional Limitations

Minor	Functional capacity adequate to conduct normal activities and self-care Walking capacity of more than one hour No aids needed
Moderate	Functional capacity adequate to perform only a few or none of the normal activities and self-care Walking capacity of about one half hour Aids such as a cane are needed
Severe	Largely or wholly incapacitated Walking capacity of less than half hour or unable to walk or bedridden Aids such as a cane, a walker or a wheelchair are required

Variable	**Definition**
Mobility and Stability	
Preserved mobility and stable joint	Preserved mobility is equivalent to minimum range of movement from 0 to 90. Stable or not lax is equivalent to an absence of slackness of more than 5mm in the extended joint.
Limited mobility and /or stable joint	Limited mobility is equivalent to a range of movement less than 0 to 90. Unstable or lax is equivalent to the presence of slackness of more than 5mm in the extended joint.
Radiology	
Slight	Ahlback grade 1.
Moderate	Ahlback grade II and III.
Severe	Ahlback grade IV and V.

Appendix 2

Primary Hip Replacement Surgery

Referral Proforma for GPs

Patient Details		
Name:		
NHS Number:		
Date of Birth:		
Address:		
Clinician Details		
Name of Referring Clinician:		**Date:**
Practice ID:		
Practice Telephone Number:		

Please enter referral letter text here (optional).

Please state clearly if the referral is outside of policy and a specialist opinion is required, giving relevant clinical information i.e. the patients BMI is >35.

Appendix 2

Primary Knee Replacement Surgery

Referral Proforma for GPs

Patient Details		
Name:		
NHS Number:		
Date of Birth:		
Address:		
Clinician Details		
Name of Referring Clinician:		**Date:**
Practice ID:		
Practice Telephone Number:		

Please enter referral letter text here (optional).

Please state clearly if the referral is outside of policy and a specialist opinion is required, giving relevant clinical information i.e. the patients BMI is >35.

Appendix 3

Referral criteria elective Hip and Knee Replacements

Patients should meet all the following criteria and referred appropriately:

Referral should be made when other pre-existing medical conditions have been optimised **AND** conservative measures have been exhausted and failed.

Please refer to the referral criteria for Symptomology in the table overleaf.

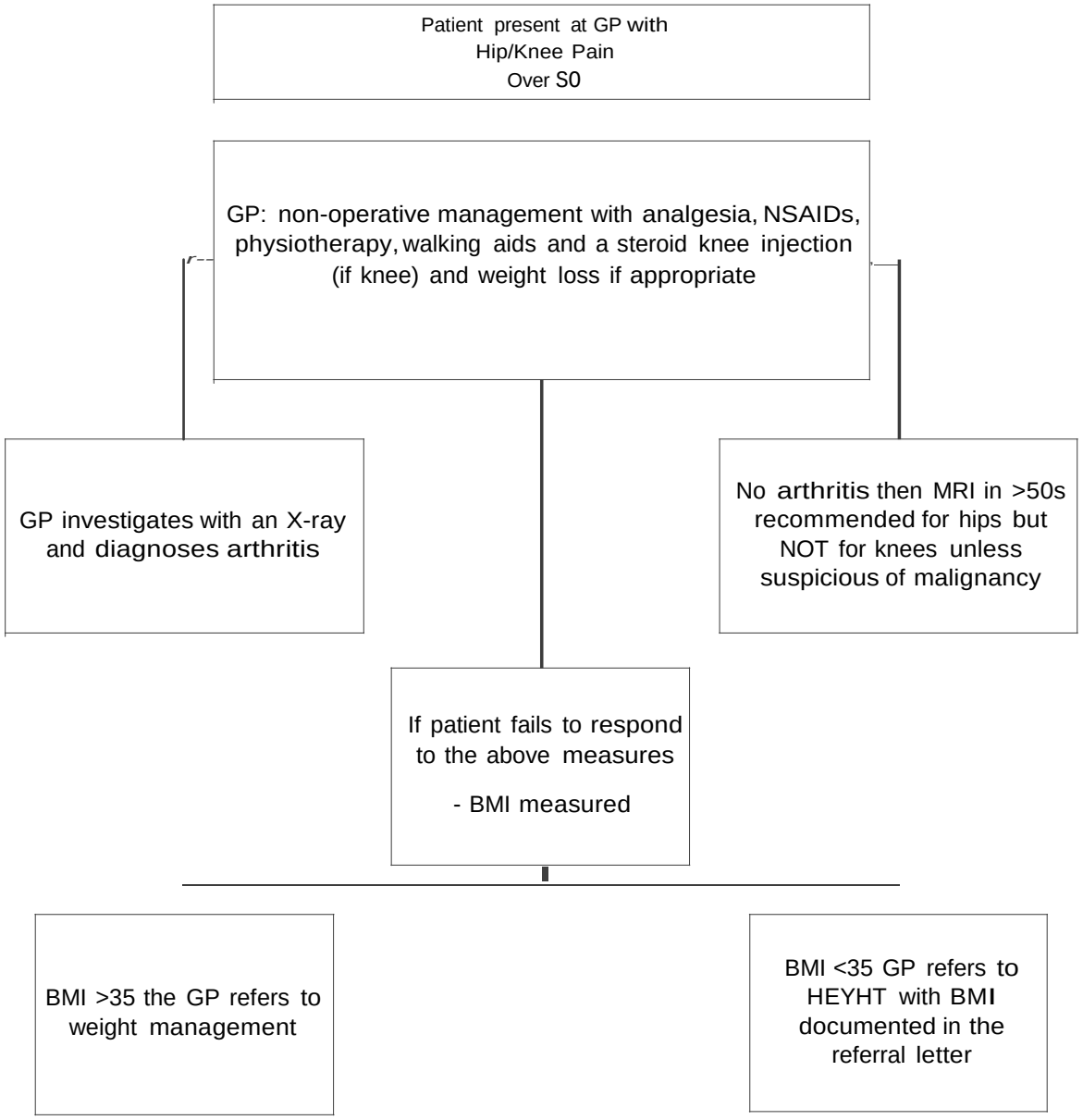
NHS Number: _____

Referral Criteria	*Tick boxes as appropriate*
The initial non-surgical management of hip and knee pain due to osteoarthritis **has been provided**, i.e. a package of care that may include weight management and weight reduction, activity modification, patient specific exercise programme, adequate doses of non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics, joint injections, introducing walking aids, and other forms of physical therapies.	☐
Patient has a Body Mass Index of <35. (If the patients BMI is >35 patients should be referred for weight management interventions and upon 6 months of documented weight loss if the patient fails to lose weight to a BMI <35 then consider referral through IFR process.	☐
Patient has moderate to severe persistent pain not adequately relieved by an extended course of non-surgical management (including weight management)	☐
If patient is a smoker, date referred to smoking cessation services **Date:** _____	
AND Clinically significant functional limitation (moderate to severe) functional limitation resulting in diminished quality of life.	☐
AND Radiographic evidence of joint damage.	☐

Appendix4

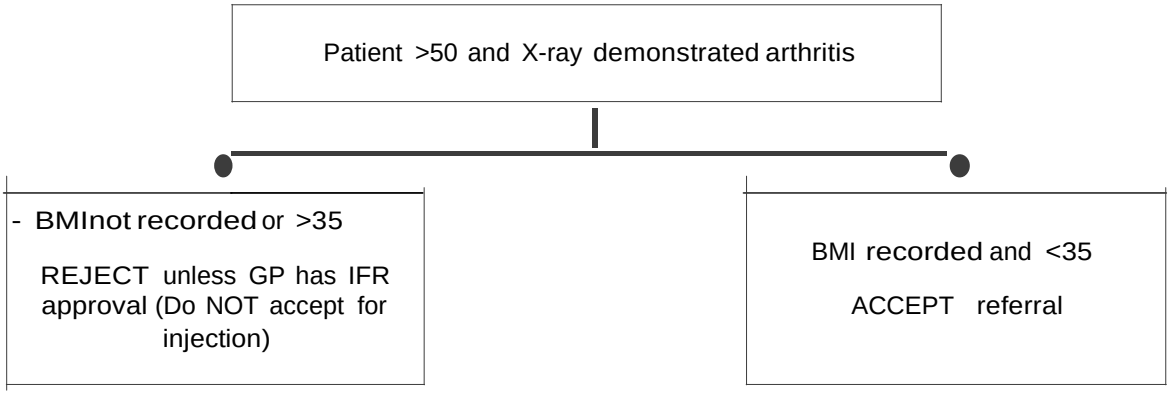
Hip and Knee replacement GP Guidance

GP Referral



Knee replacement Trust Triage

Over 50 Years

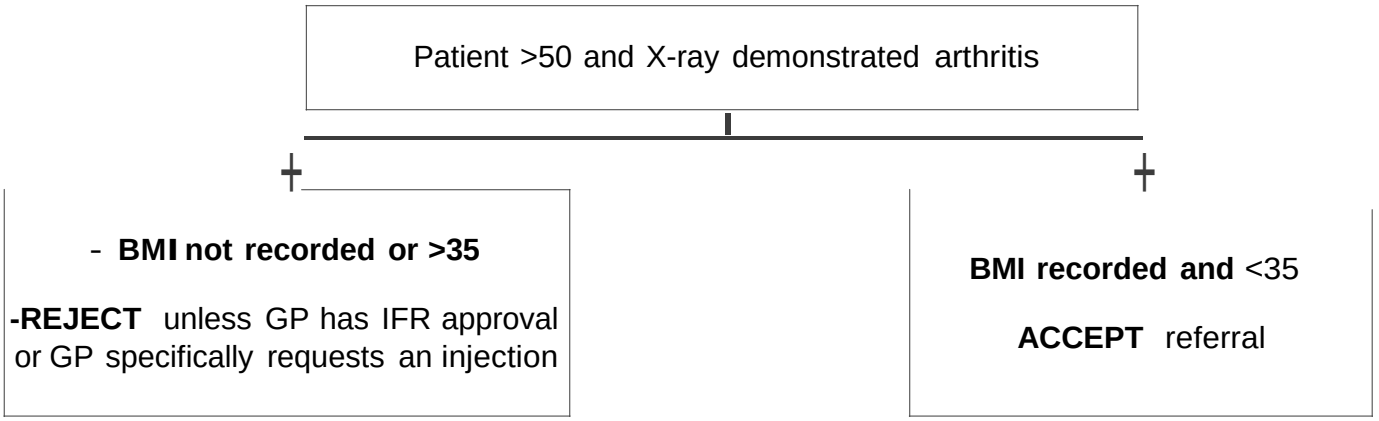


Under 50 years

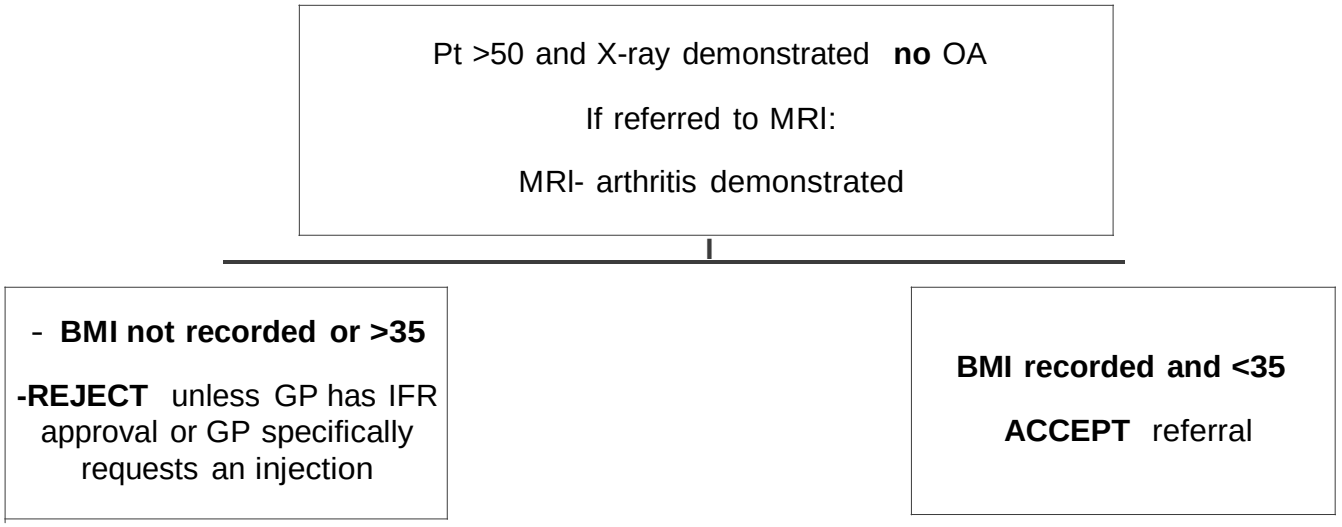
Patient <50 manage as current with x-ray then MRI if no x-ray abnormality then refer if significant pathology

Hip replacement Trust Triage

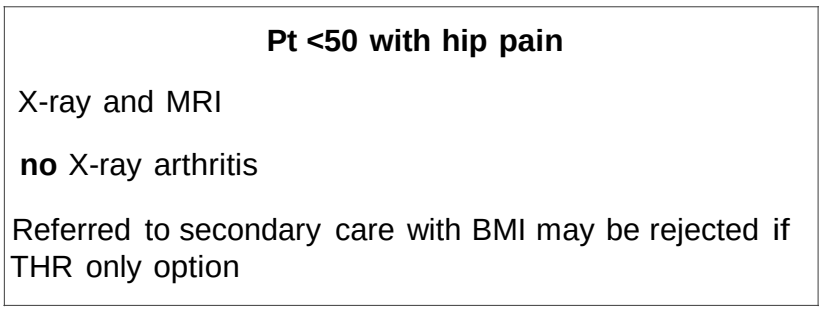
Over 50 Years



Over 50 NO Arthritis



Under 50 years with hip pain



NHS Hull CCG Patient Choice Policy Statement

Our Choice Commitments

Universal Personalised Care explains how you can now have a level of choice and control over your mental and physical health based upon 'what matters' to you rather than 'what is the matter with you'. It will help you to understand your health choices and will give you a voice that will be heard.

We are committed to offering meaningful choice to all people. As a clinical commissioning group (CCG) we have a duty to enable you to make choices, and to promote your involvement in decisions in respect of your care or treatment.

For choice to be meaningful, all people using health services commissioned by the CCG should be able to say:

- I have discussed with my GP/health care professional the different options, pros and cons including, where appropriate, whether to have treatment as part of a shared decision making conversation.
- Following agreement to progress my care, I was offered choice of where to go for my first outpatient appointment or diagnostic test, as appropriate.
- I was given an opportunity to choose a suitable alternative provider when I was going to wait longer than the maximum time specified in my legal rights.
- Information to help me make my decisions was available and I knew where to find it in a format that was accessible to me.
- I was given sufficient time to consider what was right for me.

When offered meaningful choice, you can:

- Select treatment and services that better meet your needs and preferences
- Have an improved experience of care
- Feel supported and empowered to make informed choices based on what is important to you
- Support providers to offer and improve their services around what matters to you
- Have the opportunity to explore all care or treatment options, along with an understanding of their risks and benefits

We will do this by ensuring we meet the commitments in The NHS Choice Framework, which sets out the choices available to you as a patient in the NHS in England; and where there are exclusions.

The framework explains:

- when you have choices about your health care
- where to get more information to help you choose
- how to complain if you are not offered a choice

In some circumstances there is a legal right to choice, and you must be given these choices by law. In other circumstances there is not a legal right to choice, but we are committed to you being offered choice about your care, based on what is available locally.

The choices available to you are:

- Choice of GP and GP practice
- Choice of where to go for your first outpatient appointment
- Right to ask to change hospital if you have to wait longer than the maximum waiting times (18 weeks, or two weeks to see a specialist for cancer)
- Choice of who carries out a specialist test
- Choice of maternity services
- Choice of community services
- Choice to take part in health research
- Choice to have a personal health budget
- Choice to access required treatment in another European Economic Area country

Feedback, queries or complaints

If you have had a positive or negative experience or feel your choices and options were not explained clearly, please let us know by sharing your experiences with us through our Patient Advice and Liaison Team on 01482 335409, by email via HullCCG.Pals@nhs.net or by writing to us using our freepost address Patient Relations, Freepost Plus RTGL-RGEB-JABG, NHS HULL Clinical Commissioning Group, 2nd Floor, Wilberforce Court, Alfred Gelder Street, Hull, HU1 1UY.

This information helps us to review services and can help other people when they are making their choices.

If you do not feel that you have been offered the choices outlined in this statement, in most cases it might be helpful to speak to the health care professional responsible for your treatment in the first instance. However, if you do not feel comfortable doing this or if you are unsatisfied with the outcome of this conversation, you may wish to discuss your situation/complaint further - contact our Patient Advice and Liaison Team on the details above.

You are also able to contact NHS England, details of how to contact NHS England or NHS Improvement are set out in Section 13 of The NHS Choice Framework

Further information and support available to our patients / referrers

There are lots of places where you can find information when making decisions about care and treatment:

- Our website www.hullccg.nhs.uk where you can find lots more information about our services

- The NHS Long Term Plan has been drawn up by frontline staff, patient groups and national experts to provide the long-term goals to improve care quality and outcomes and prevent health inequalities by placing the patient at the centre of the care they receive.

- Universal Personalised Care - this publication explains how you can now have a level of choice and control over your mental and physical health based upon 'what matters' to you rather than 'what is the matter with you'. It will help you to understand your health choices and will give you a voice that will be heard.

- The NHS.uk website : this website can help you when making important health decisions, including which GP surgery you register with and which hospital you attend for treatment. It provides tools and resources that help you look at your options and make the right decision.

- The My NHS website allows you to compare health and care services, including hospitals, GP practices and consultant surgeons, helping you to choose.
- Information is available on the NHS England patient choice webpages, including a patient leaflet to help you to understand the choices available to you. The NHS Constitution tells you what you can and should expect when using the NHS. The NHS Constitution is also available in an Easy Read version for download. Audio and Braille versions are available on request.
- The Care Quality Commission checks many care organisations in England to ensure they are meeting national standards and then shares its findings with the public. You can also call its National Customer Service Centre: Tel: 03000 616161 (Mon to Fri, 8.30am - 5:30pm).
- Healthwatch is an independent consumer champion for health and social care in England. It operates as Healthwatch England at national level and as local Healthwatch at local level.
- Rightcare is a NHS England supported programme committed to delivering the best care by ensuring that you can access the right care in the right place at the right time to ensure that the best possible care is delivered.

The Shared Decision Making Programme Is committed to ensuring that people are supported to a) understand the care, treatment and support options available and the risks, benefits and consequences of those options, and b) make a decision about a preferred course of action, based on evidence-based, good quality information and their personal preferences

Access to Infertility Treatment –

Commissioning Policy Document

Yorkshire and Humber

Adopted by
NHS Hull CCG

September 2020 – April 2023

Document Title:	Access to Infertility Treatment – Commissioning Policy Document Yorkshire and Humber
Author/Lead **Name:** **Job Title:**	 Michelle Thompson Assistant Director Women's and Children's Services
Version No:	V11
Latest Version Issued On	February 2020
Supersedes:	All previous Access to infertility treatment policies
Date of Next Review:	April 2023
Completion Equality Impact Statement **Name:** **Job Title:** **Date:**	 Philippa Doyle Hempsons Solicitors August 2018 (Update based on notes)
Target Audience:	Public
Dissemination:	Internet

APPROVAL RECORD		
	Committees / Groups / Individual	**Date**
Consultation:	Yorkshire and Humber Expert Fertility Panel	2 March 2017 31 January 2018 25 June 2018 25 January 2019
	Hempsons Solicitors	August 2018
Ratified by Committees:	Planning and Commissioning Committee Hull CCG	7 November 2020

CHANGE RECORD			
Version	**Author**	**Nature of Change**	**Uploaded**
		Update as per local CCG	

Any locally held old paper copies must be destroyed. ***When this document is viewed as a paper copy, the reader is responsible for checking that it is the most current version. This can be checked on the NHS Hull CCG website***

Commissioning Policy Statement:

Commissioning

This document represents the commissioning policy of NHS Hull CCG for the clinical pathway which provides access to specialist fertility services. This commissioning policy has been developed in partnership with the Yorkshire and Humber Expert Fertility Panel. It is intended to provide a framework for the commissioning of services for those couples who are infertile and require infertility interventions.

The policy was developed jointly by Clinical Commissioning Groups in the Yorkshire and Humber area and provides a common view of the clinical pathway and criteria for commissioning services which have been adopted by NHS Hull CCG.

Funding

The policy on funding of specialist fertility services for individual patients is a policy of NHS Hull CCG and is not part of the shared policy set out in the rest of this document. The number of full IVF cycles currently funded by the NHS Hull CCG for patients who meet the access criteria set out in the shared policy is 3 cycles. This is unchanged from the previous funding policy in March 2016. This policy will be updated in accordance with the review period of the policy or earlier should sufficient changes in practice or evidence base require it.

Immigration Health Surcharge; Right to Assisted Conception Services

Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, assisted conception services are no longer included in the scope of services.

However, the October 2019 Guidance on Implementing Overseas Visitors Regulations says that: 'Where two people are seeking assisted conception services with NHS funding, and one of the two people is covered by health surcharge arrangements and the other is ordinarily resident in the UK and therefore not subject to charge, the services required by the health surcharge payer will be chargeable. Any services required by the ordinarily resident person will continue to be freely available, subject to the established local or national commissioning arrangements'.

Our eligibility criteria for access to assisted conception services relates to couples rather than individuals. Therefore in light of this guidance, to enable the ordinarily resident person to have freely available access to services, where at least one partner is eligible for these services, the couple will be considered as eligible for services.

Working group membership and Conflicts of Interest

See appendices E and F

For Further Information about this policy.

Please contact NHS Hull Clinical Commissioning Group.

Contents

1. Aim of Paper

1.1 This document represents the commissioning policy for specialist fertility services for adults registered with a Clinical Commissioning Group (CCG) in the Yorkshire and Humber region.

1.2 The policy aims to ensure that those most in need in keeping with current eligibility, are able to benefit from NHS funded treatment and are given equitable access to specialist fertility services across the Yorkshire and Humber Area, by identifying the clinical care pathway and relevant access criteria.

2. Background

2.1 On April 1st, 2013 Clinical Commissioning Groups (CCGs) across the Yorkshire and the Humber regions adopted the existing Yorkshire and the Humber Fertility policy[1]. In February 2013 NICE published revised guidance[2] which was reviewed and updated in 2016.

2.2 CCGs across the Yorkshire and the Humber agreed to work collaboratively to update the existing policy in light of the new NICE guidance and changing commissioning landscape.

2.3 In this policy document infertility is defined as:

Definition of Infertility:

The inability to conceive through regular sexual intercourse for a period of 2 years in the absence of known reproductive pathology, or less than 2 years if there is specific reproductive pathology identified.

Where attempting to conceive by regular sexual intercourse is not possible (for example for people with a physical disability, people with psychosexual disorders or transgender and same sex couples) this will be considered as inability to conceive for the purposes of this policy.

2.4 Fertility problems are common in the UK and it is estimated that they affect 1 in 7 couples with 80% of couples in the general population conceiving within 1 year, if:

- The woman is aged under 40 years and
- They do not use contraception and have regular sexual intercourse (NICE 2013)

Of those who do not conceive in the first year about half will do so in the second year (cumulative pregnancy rate is 90%).

The remaining 10% of couples will be unable to conceive without medical intervention and are therefore considered infertile.

2.5 In 25% of infertility cases, the cause cannot be identified. However, it is thought that in the remaining couples about 30% of cases are due to the male partner being unable to produce

[1] Yorkshire and the Humber Commissioning Policy for Fertility Services, 2010.

[2] Fertility: Assessment and treatment for people with fertility problems 2012, NICE Clinical Guideline 156.

or ejaculate sufficient normal sperm, 30% are due to problems found with the female partner such as failure to ovulate or blockage to the passage of the eggs, and 10% are due to problems with both partners.

2.6 The most recent DH costing tool estimates that there are 98 attendances at a fertility clinic for every 10,000 head of population. In Yorkshire and the Humber, this could range between 4000 and 5000 attendances per year which would result in approximately 1450 couples likely to be assessed as eligible for IVF treatment.

2.7 Specialist fertility services include IUI, ICSI and IVF. They may also include the provision of donor sperm and donor eggs. The majority of treatment in the UK is statutorily regulated by the Human Fertility and Embryo Authority (HFEA)[3]. All specialist providers of fertility services must be licensed with the HFEA in order to be commissioned under this policy.

2.8 NICE Clinical Guidelines 156 (2013) covering infertility recommends that:

> Up to three full cycles of IVF will be offered to eligible couples where the woman is aged between 18 and 39 and 1 cycle for eligible couples where the woman is aged 40 - 42.

NHS Hull CCG will fund 3 cycles of IVF treatment. Where an individual feels that they have exceptional circumstances that would merit consideration of an additional cycle being funded by the NHS they should speak to their doctor about submitting an individual funding request to their local CCG.

2.9 In addition to commissioning effective healthcare, CCGs are required to ensure that resources are allocated equitably to address the health needs of the population. Therefore CCGs' will need to exercise discretion as to the number of cycles of IVF that they will fund up to the maximum recommended by NICE.

3. Clinical Effectiveness

It is considered to be clinically effective by NICE to offer up to 3 stimulated cycles of IVF treatment to couples where the woman is aged between 18 – 39 and 1 cycle where the woman is aged between 40 – 42 and who have an identified cause for their infertility or who have infertility of at least 2 years duration.

4. Cost Effectiveness

4.1 Evidence shows (NICE 2013) that as the woman gets older the chances of successful pregnancy following IVF treatment falls. In light of this, NICE has recommended that the most cost effective treatment is for women aged 18 – 42 who have known or unknown fertility problems.

4.2 As research within this field is fast moving, new interventions and new evidence needs to be considered on an on-going basis to inform commissioning decisions.

[3] https://www.hfea.gov.uk/

4.3 Risks

Fertility treatment is not without risks. A summary of potential risks is outlined below:

Risks

- There are risks of multiple pregnancies during fertility treatment, which is associated with a higher morbidity and mortality rate for mothers and babies.
- Women who undergo fertility treatment are at slightly higher risk of ectopic pregnancy.
- Ovarian hyper stimulation, which is a potentially fatal condition, is also a risk. The exact incidence of this has not been determined but the suggested number is between 0.2 – 1% of all assisted reproductive cycles.
- Current research shows no cause for concern about the health of children born as the result of assisted reproduction.
- A possible association between ovulation induction therapy and ovarian cancer in women who have undergone treatment is uncertain.
- Further research is needed to assess the long-term effects of ovulation induction agents.

5 Description of the Treatment

5.1 Principles of Care

5.1.1 Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.

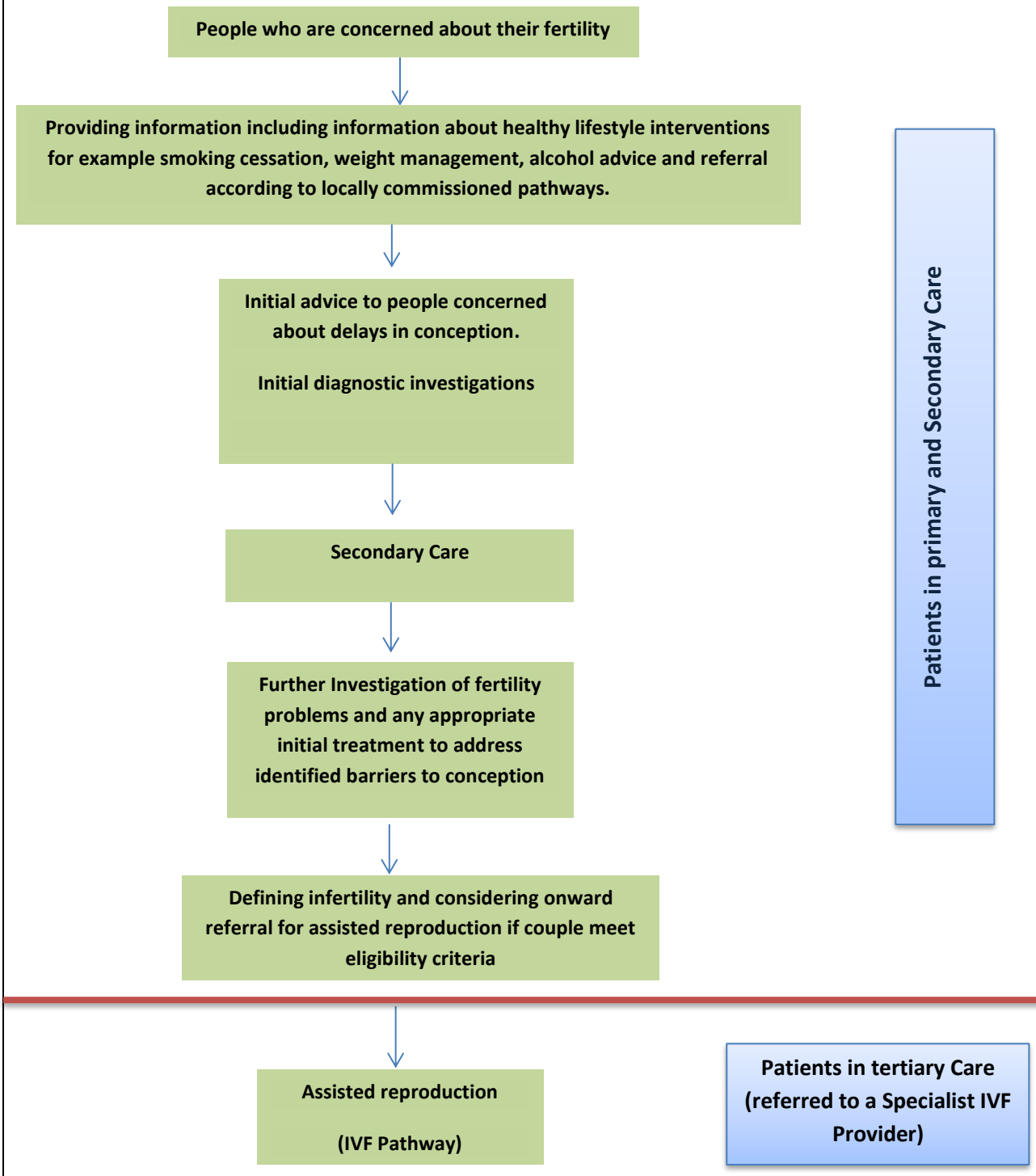
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Sensitive to those with additional needs e.g. physical or cognitive, or those for whom English is not their first language.

5.1.3 As infertility and infertility treatments have a number of psychosocial effects on couples, access to psychological support prior to and during treatment should be considered as integral to the care pathway.

5.2 The Care Pathway for fertility investigation and referral (fig, 1)



The Care pathway for fertility investigation and referral will take account of NICE guidance.

5.2.1 Treatment for infertility problems may include counselling, lifestyle advice, drug treatments, surgery and assisted conception techniques such as IVF.

- Providers of specialist fertility services are expected to deliver appropriate interventions to support lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. Recommendations covering screening, brief advice and onward referral are outlined in NICE Public Health Guidance (PH49) and, specifically in relation to fertility and pre-conception, smoking (PH 26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24).

- Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, and physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle.

- Offer those who would benefit from this, a referral to local wellbeing services and/or locally commissioned lifestyle services. For those that are unable or do not want to attend support services direct them to appropriate self-help information such as the national 'One You' website or local websites.

- Record this in the hand-held record or accepted local equivalent.

The care pathway (fig 1) begins in primary care, where the first stage of treatment is general lifestyle advice and support to increase a couple's chances of conception without the need for medical intervention.

If primary care interventions are not effective, initial assessment such as semen analysis will take place. Following these initial diagnostics, it may be appropriate for the couple to be referred to secondary care services where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. It may be appropriate at this stage for the primary care clinician to consider and discuss the care pathway and potential eligibility for IVF. It may also be appropriate for healthy lifestyle interventions to be further discussed.

If secondary care interventions are not successful and the couple fulfils the eligibility criteria in section 6.0, they may then be referred through to specialist care for assessment for assisted conception techniques, such as IVF, DI, IUI, and ICSI.

5.2.2 IVF involves:

- Controlled ovarian stimulation
- Monitoring the development of the eggs in the ovary
- Ultrasound guided egg collection from the ovary
- Processing of sperm
- Production of a fertilized embryo from sperm and egg cells in the laboratory
- Culture of embryos to blastocyst (*if clinically appropriate*)
- Single embryo transfer (subject to multiple birth minimisation policy)
- Use of progesterone to make the uterus receptive to implantation

- Transfer of selected embryos and freezing of those suitable but not transferred

The panel will review annually, following the HFEA[4] annual review via their traffic light report, any other emerging technologies which may then need consideration for incorporation in this policy.

5.3 Definition of a Full Cycle

Full cycle is the term used to define a full IVF treatment; it should include one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) (NICE 2013). Or

The definition of a single full treatment cycle is the replacement of a fresh embryo and subsequent sequential replacement of all frozen embryos derived from the cycle until pregnancy is successful or harvested embryos have been exhausted.

Adherence in this way to the NICE guidelines would encourage and not disadvantage patients agreeing to single embryo transfer.

5.4 Frozen Embryo

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use within the cycle.

All stored and viable embryos should be used before a new cycle commences. This includes embryos resulting from previously self-funded cycles.

5.5 Abandoned Cycles

An abandoned IVF/ICSI cycle is defined as the failure of egg retrieval, usually due to lack of response (where less than three mature follicles are present) or excessive response to gonadotrophins; failure of fertilisation and failure of cleavage of embryos. Beyond this stage, a cycle will be counted as complete whether or not a transfer is attempted. One further IVF/ICSI cycle only will be funded after an abandoned cycle. Further IVF/ICSI cycles will not be offered after any subsequent abandoned cycles.

5.6 IUI and DI

IUI and DI are separate from IVF treatment; however, the couple may then access IVF treatment if appropriate.

5.6.1 People with physical disabilities, psychosexual problems, or other specific conditions with infertility (as defined in section 2.3 Definition of Infertility):

Where a medical condition exists, such as physical disability up to 6 cycles of IUI may be funded, followed by further assisted conception if required. In some circumstances, IUI may be impractical and so is not a requirement for further fertility treatment.

[4] https://www.hfea.gov.uk/

5.6.2 IUI and DI in same-sex relationships:
Up to 6 cycles of IUI will be funded as a treatment option for people in same-sex relationships, followed by further assisted conception if required.

5.6.3 People with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse:
IUI either with or without ovarian stimulation will not be funded routinely (exceptional circumstances may include, for example, when people have social, cultural or religious objections to IVF), instead couples should try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered, in keeping with current NICE guidance.

5.6.4 Gonadotrophin Therapy - for women with anovulatory infertility, ovulation induction with gonadotrophin therapy should be funded for up to 6 cycles, with or without IUI depending on the circumstances of the couple.

5.6.5 Donor Gametes including azoospermia:
Patients who require donor gametes will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria is still met. If it is anticipated that there will be difficulty finding a suitable donor exceptionality would need to be considered. At this point consideration may need to be given to sourcing from alternative providers via IFR.

Donor Sperm

Where clinically indicated up to six cycles of donor insemination will be offered. This is dependent on the availability of donor sperm which is currently limited in the UK.
The cost of donor sperm is included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the CCG.

Donor Eggs

Patients eligible for treatment with donor eggs, in line with NICE recommendations, will be placed on the waiting list for treatment with donor eggs. Unfortunately, the availability of donor eggs remains severely limited in the UK. There is, therefore, no guarantee that eligible patients will be able to proceed with treatment.

5.7 Gametes and Embryo Storage

The cost of egg and sperm storage will be included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the CCG. Storage will be funded by the CCG for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter. This will be explained by the provider prior to the commencement of treatment. Following this period continued storage may be self-funded.

Any embryos frozen prior to implementation of this policy will be funded by the CCG to remain frozen for a maximum period of 3 years from the date of policy adoption.
Any embryo storage funded privately prior to the implementation of this policy will remain privately funded.

5.8 HIV/HEP B/ HEP C

People undergoing IVF treatment should be offered testing for HIV, hepatitis B and hepatitis C (NICE 2013).

People found to test positive for one or more of HIV, hepatitis B, or hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE 2013).

5.9 Surrogacy

Any costs associated with use of a surrogacy arrangement will not be covered by funding from CCGs. We will, however, fund provision of fertility treatment (IVF treatment and storage) to identified (fertile) surrogates, where this is the most suitable treatment for a couple's infertility problem and the couple meets the eligibility criteria for specialist fertility services set out in this policy.

5.10 Single Embryo Transfer

Please refer to 5.3 for the definition of a full cycle.

Multiple births are associated with greater risk to mothers and children and the HFEA[5] therefore recommends that steps are taken by providers to minimize them. This is currently achieved by only transferring a single embryo for couples who are at high risk.

We support the HFEA guidance on single embryo transfer and will be performance monitoring all specialist providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies.

We commission ultrasound guided embryo transfer in line with NICE Fertility Guideline.

5.11 Counselling and Psychological Support

As infertility and infertility treatment has a number of negative psychosocial effects, access to counselling and psychological support should be offered to the couple prior to and during treatment.

5.12 Sperm washing and pre-implantation diagnosis

Sperm washing and pre-implantation genetic diagnosis are not treatments for infertility and fall outside the scope of this policy. Prior approval is required.

5.13 Service Providers

Providers of fertility treatment must be HFEA registered and comply with any service specification drawn up by Yorkshire and the Humber Clinical Commissioning Groups.

6.0 Eligibility Criteria for Treatment

6.1 Application of Eligibility Criteria

Eligibility criteria should apply at the point at which patients are referred to specialist care (with the exception of 6.10, which should be undertaken within specialist care). Couples must meet the definition of infertility as described in section 2.3.

[5] https://www.hfea.gov.uk/

6.2 Overarching Principles

6.2.1 All clinically appropriate individuals/couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation.

6.2.*2* Assisted conception is only funded for those couples who meet the eligibility criteria.

6.2.3. Treatment limits are per couple and per individual. Referrals should be as a couple and include demographic information for both partners in heterosexual and same-sex couples.

6.3 Existing Children

Neither partner should have any living children (this includes adopted children but not fostered) from that or any previous relationship.

6.4 Female Age

Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment.

The woman intending to become pregnant must be between the ages of 18 – 42 years. No new cycle should start after the woman's 43rd birthday. Referrers should be mindful of the woman's age at the point of referral and the age limit for new cycles.

Women aged 40–42 years who meet the eligibility criteria for infertility in Section 2.3, will receive 1 full cycle of IVF, with or without ICSI, provided the following criteria are fulfilled:

- they have never previously had IVF treatment and there is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less
- there has been a discussion of the additional implications of IVF and pregnancy at this age
- where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, women aged between 40-42 should be referred directly to a specialist team for IVF treatment

6.5 Pre – Referral Requirement for Specialist Care

6.5.1 Female BMI

The female patient's BMI should be between 19 and 30 prior to referral to specialist services. Patients with a higher BMI should be referred for healthy lifestyle interventions including weight management advice. Patients should not be re-referred to specialist services until their BMI is within the recommended range.

6.5.2 Smoking Status

GP should discuss smoking with couples prior to referral to secondary care, support their

efforts in stopping smoking by referring to a smoking cessation programme.

People should be informed that maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment.

6.6 Reversal of Sterilisation

We will not fund IVF treatment for patients who have been sterilised or have unsuccessfully undergone reversal of sterilisation.

6.7 Previous Cycles

Previous cycles whether self-funded or NHS funded will be taken into consideration when assessing a couple's ability to benefit from treatment and will count towards the total number of cycles that may be offered by the NHS. This includes where either person has had a previous cycle with a previous partner.

6.8 Length of Relationship

The stability of the relationship is very important with regards to the welfare of children; as such couples must have been in a stable relationship for a minimum of 2 years and currently co-habiting to be entitled to treatment.

6.9 Welfare of the child

HFEA guidance concerning the welfare of the child should be followed.

Appendix, A

Abbreviations

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**
CCG	**Clinical Commissioning Group**

Appendix, B
Definitions

Term	Definition	Further information
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 is 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

Appendix C, Equality Impact Assessment

Title of policy	Fertility Policy	
Names and roles of people completing the assessment	Philippa Doyle Hempsons Solicitors	
Date of Assessment from – to Review date	Aug 2018 Nov 2019	Feb 2021 April 2023

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the relevant CCG to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about the fertility policy. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for specialist fertility treatment.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
Give details of evidence, data or research used to inform the analysis of impact	NICE fertility guidance https://www.nice.org.uk/guidance/cg156 (accessed 3/3/17)

3. Consultation, engagement	
Give details of all consultation and engagement activities used to inform the analysis of impact	Discussion with panel of experts in Yorkshire and Humber representing commissioners and providers. All changes from the previous policy are in line with NICE guidelines which have had extensive engagement and consultation. See https://www.nice.org.uk/guidance/cg156/history

4. Analysis of impact

This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to;

eliminate unlawful discrimination; advance equality of opportunity; foster good relations

	Are there any likely impacts? **Are any groups going to be affected differently?** **Please describe.**	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	Yes. IVF is only available to women aged between 18 and 42. As a woman ages the chances of successful pregnancy fall.	Both	Action cannot be taken to prevent this it is therefore incumbent simply to ensure clear age limitations are identified
Carers	No		
Disability	Yes. The policy has been enhanced to offer funding to couples who by reason of disability cannot conceive naturally	positive	The fact of this new change and opportunity to such couples can be publicised
Sex	No		
Race	No		
Religion or belief	No		
Sexual orientation	Yes. The policy has been enhanced to offer funding to couples in a same sex relationship without having to demonstrate they have self-funded other trials	positive	The fact of this new change and opportunity to such couples can be publicised
Gender reassignment	Yes	positive	Gender reassignment is specifically referenced in the definition of infertility
Pregnancy and maternity	Yes. The policy enhances the ability to access fertility treatment and the potential	positive	

	to achieve pregnancy		
Marriage and civil partnership	No		
Other relevant group			

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Each CCG to monitor individual funding requests for this procedure and identify if there are issues with the policy which require a policy refresh.		
Lead Officer	Insert CCG	**Review date:**	xx2021

6.Sign off on behalf of the local CCG			
Lead Officer			
Director		**Date approved:**	

Appendix D, Version Control

VERSION	DATE	AUTHOR	STATUS	COMMENT
V11	Feb 19	H Lewis and M Thompson		Changes to page 3 – immigration health surcharge – reworked following updated advice Moved list of panel members to Appendix for easier access to contents of document
V10	November 2019	M Thompson on behalf of Panel		Changes to: - Page 2 & 3 – Immigration Health Surcharge – sentences reworded - 6.5.2 – Smoking Status – sentences reworded - 6.7 – Previous Self-funded Cycles – titles changed to Previous Cycles - sentences reworded - 6.8 – Previous Self-Funded Cycles - sentence removed - 6.10 – Welfare of the Child - sentence reworded

V9	January 2019	M Thompson on behalf of Panel	Draft	Changes to: - Funding - Immigration health surcharge – sentence added - 1.2 - sentence reworded - 2.3 – change of order in sentence in brackets - 5.2 – sentence included after pathway - 5.2.1 – third bullet point, wording changed - 5.2.2 – first two bullet points replaced with Controlled Ovarian Stimulation - 5.4 – heading changed to Frozen Embryo - 5.6.1 – sentence reworded - 5.6.3 – link to mild male factor infertility removed - 5.6.3 – wording added - 5.6.4 – spelling corrected - 5.6.5 – new paragraph inserted - 5.6.5 - Donor Sperm - sentence reworded - 5.7 – sentence reworded - 6.2.1 and 6.2.2 - swopped around and reworded - 6.5.2 – title changed - 6.5.2 – sentence reworded - 6.9 – sentence reworded

v8	June 2018	M. Thompson on behalf of Panel	Draft	Changes to:- - 2.3 Definition of Infertility - 5.2.2. – IVF involves – additional bullets added - 5.3 – Definition of cycles – removed sentence in brackets - 5.6.4 - Gonadotrophin Therapy added - 5.6.5 – renumbered – added “all couples” where this is a clinical requirement (to replace the reference to male azoospermia) added limited to UK Added additional sentence - 6.5 – title updated to – Pre-referral requirement to specialist care - 6.5.2 – non-smokers section added. - 6.9 – Updated to include the stability of the relationship
v7	Jan 2018	M. Thompson on behalf of Panel	Draft	- Changes to 5.2 pathway - Changes to funding – adding refugees and asylum seekers - Removal of summary of CCGs - 2.3 – clarification of definition of infertility - 6.7 updated to NHS Funded full cycles - 6.10 – added section - Change tertiary to specialist throughout the policy.

Review 2017	22.2.17	F Day on behalf of panel	Final draft	- changes to the definition of infertility for same sex and patients with psychosexual issues and disabilities to be more clear - the addition of public health requirements for providers in line with NICE guidance - clarification of the definition of an abandoned cycle - sections on intrauterine insemination and also egg donation updated in line with NICE guidance - Addition of People with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse in line with NICE guidance - wording changed in various sections based on patient feedback to be more clear, not materially changed in content - embryo transfer wording updated to reflect NICE guidance - Addition of definition of low ovarian reserve (previously undefined)

Appendix E

Panel Members: (March 2017)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Chris Edward	Accountable Officer - Rotherham CCG
Dr Steve Maguiness	Medical Director - The Hull IVF Unit, Hull Women and Children's Hospital and honorary contract with HEY
Dr John Robinson	Scientific Director - IVF Unit, Hull and East Yorkshire Hospitals FT
Prof Adam Balen	Professor of Reproductive Medicine and Surgery - Leeds Teaching Hospitals NHS Trust
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Richard Maxted	Service Manager, Directorate of Obstetrics, Gynaecology and Neonatology - Sheffield Teaching Hospital NHS Trust
Dr Margaret Ainger	Clinical Director for Children, YP and Maternity - NHS Sheffield CCG
Dr Bruce Willoughby	Lead for Planned Care - NHS Harrogate and Rural District CCG
Dr Clare Freeman	Medical Advisor to IFR Panel - South Yorkshire and Bassetlaw CCGs

Panel Members (amendments January 2018)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Dr Bruce Willoughby	Lead for Planned Care - NHS Harrogate and Rural District CCG
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT
Karen Thirsk	Fertility Policy Manager – NHS England
Brigid Reid	Chief Nurse – NHS Barnsley CCG
Helen Lewis	Head of Planned Care – NHS Leeds CCG.
Clare Freeman	Lead Medical Advisor – Sheffield CCG.

Panel Members (amendments June 2018)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT
Brigid Reid	Chief Nurse – NHS Barnsley CCG

Helen Lewis	Head of Planned Care – NHS Leeds CCG
Dr Bryan Power	(GP) - NHS Leeds CCG
Adam Balen	(Consultant) - Leeds Fertility
Clare Freeman	Lead Medical Advisor – Sheffield CCG

Panel Members (amendments January 2019)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Martine Tune	Acting Chief Nurse – NHS Barnsley CCG
Liz Micklethwaite	Business Manager IFR - NHS Leeds CCG

Commissioner Final Proof Read Panel (Amendments November 2019)

Michelle Thompson	Assistant Director, Women's and Children's Services – NHS North East Lincolnshire CCG
Helen Lewis	Head of Planned Care – NHS Leeds CCG
Clare Freeman	Lead Medical Advisor – Sheffield CCG
Karen Leivers	Head of Strategy and Delivery, Planned Care - Doncaster CCG
Debbie Stovin	Commissioning Manager – Elective Care – Sheffield CCG

Appendix F Relevant Conflicts of Interest Declared:

Dr Steve Maguiness:

IVF in Hull is provided by a private company (ERFS Co Ltd), of which I am a Director and employee.

Prof Adam Balen:

NHS Consultant in Reproductive Medicine and Clinical lead for the Leeds Centre for Reproductive Medicine, which performs all fertility treatments funded by the NHS. Partner in Genesis LLP, the private arm of the Leeds Centre for Reproductive Medicine, which performs self-funded fertility treatments using identical protocols to the NHS. Chair, British Fertility Society. Chair, NHS England IVF Pricing Development Expert Advisory Group. Chair World Health Organisation Expert Working Group on Global Infertility Guidelines: Management of PCOS. Chair, British Fertility Society. Consultant for ad hoc advisory boards for Ferring Pharmaceuticals, Astra Zeneca, Merck Serono, Gideon Richter, Uteron Pharma. Research funding received in the past. Pharmasure / IBSA- Key note lecture at ESHRE 2016 & hospitality to attend meetings. OvaScience- Member of international ethics committee. Clear Blue National medical advisory board. IVI, UK- Chair, Clinical Board

Virginia Beckett FRCO:

I have a private practice where I see fertility patients.

I have received sponsorship from Pharmasure, Ferring & Serono to attend conferences.

General Commissioning Policy

<table>
<tr><td>Treatment</td><td colspan="2">Secondary care referral</td></tr>
<tr><td>For the treatment of</td><td colspan="2">Tendinopathies and musculoskeletal conditions</td></tr>
<tr><td>Background</td><td colspan="2">From April 2013 NHS England took over responsibility for commissioning activity in primary care, where initial conservative treatment takes place. NHS Hull CCG is responsible for commissioning activity in secondary care, and this policy sets out the referral criteria for musculoskeletal conditions and tendinopathies.
NHS Hull CCG will commission routine referrals to secondary care for those patients meeting the referral criteria below and routine surgical treatment for those patients with severe symptoms in whom all conservative treatments have been tried and failed.
However approval for extracorporeal shock wave therapy (ESWT) in secondary care must be requested via the IFR process because the benefits and risks are uncertain and there is a lack of long term outcome data.</td></tr>
<tr><td>Commissioning position</td><td>Site</td><td>Criteria for Referral to Secondary Care</td></tr>
<tr><td></td><td>Shoulder</td><td>Adhesive capsulitis (Frozen shoulder)
Conservative treatments include rest, painkillers, NSAIDs, corticosteroid injections (short term pain relief only), local anaesthetic injections, shoulder exercises and physiotherapy (stretching, massage and thermotherapy).
NHS Hull CCG will only commission referral to an orthopaedic surgeon (after an ultrasound scan) if symptoms are severe, causing significant problems and conservative treatments have not worked. Secondary care treatment options are: (i) manipulation under general anaesthetic with simultaneous injection of corticosteroid and local anaesthetic into shoulder joint OR (ii) arthroscopic capsular release via keyhole surgery and removal of any bands of scar tissue that have formed.</td></tr>
<tr><td></td><td></td><td>Supraspinatus tendonitis (impingement syndrome or painful arc syndrome)
Conservative treatments include rest, cessation of painful activity, physiotherapy, NSAIDs and analgesia. Corticosteroid and local anaesthetic injections may be used for persistent symptoms.
NHS Hull CCG will only commission referral to an orthopaedic surgeon (after an ultrasound scan) if symptoms are severe, causing significant problems and other treatments have not worked. Surgery can be done arthroscopically or as open surgery and involves removal of impinging structures and /or repair of damaged rotator cuff muscles.</td></tr>
<tr><td></td><td></td><td>Calcific tendonitis
Acute and chronic symptoms can resolve spontaneously. Conservative treatments include rest, NSAIDs, corticosteroid injections and physiotherapy
NHS Hull CCG will only commission referral to an orthopaedic surgeon (after an ultrasound scan) if symptoms are severe, causing significant problems and other treatments have not</td></tr>
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Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

		worked. Surgery can be done arthroscopically or as open surgery and involves removal of calcific deposits from the tendon. However calcification can recur (up to 18% of cases) following surgical treatment. ESWT may be commissioned after IFR approval.
	Elbow	*Medial and lateral epicondylitis (tennis or golfer's elbow)* Conservative treatments include rest, modification of activities, cold compress, painkillers, NSAIDs, orthotic support (splints), physiotherapy and corticosteroid injections (short term pain relief). NHS Hull CCG will only commission referral to a plastic or orthopaedic surgeon if pain is severe and persistent and where conservative approaches have not been effective. ESWT may be commissioned after IFR approval, or alternatively the treatment of last resort is surgical removal of the damaged bit of tendon.
	Wrist	*De Quervains Tenosynovitis* Conservative treatments include activity avoidance, splints, NSAIDs, gentle stretching and corticosteroid injections to reduce pain. Surgery is rarely required and usually reserved for patients with persisting pain. NHS Hull CCG will only commission referral to a plastic surgeon if symptoms are severe, causing significant problems and after failure of at least one steroid injection. Many cases respond to further steroid injections with a modified technique (due to variant wrist anatomy). The treatment of last resort is to surgically inspect the sheath surrounding the involved tendon or tendons, and then open the sheath to release the pressure and restore free tendon gliding.
		Flexor and extensor carpi ulnaris tendinitis Conservative management includes NSAID medications, splinting and occupational therapy, including stretching and strengthening. Diagnostic local anaesthetic injections and/or corticosteroid injections can also be helpful. Surgery is rarely required and NHS Hull CCG will only commission referral to a plastic surgeon if pain is persistent despite maximal conservative management.
	Digits	*Adult Trigger finger/thumb (stenosing tenosynovitis)* Conservative treatments include steroid injections and splinting. Steroid injections can provide permanent or temporary relief of symptoms in the majority of patients with intermittent triggering. NHS Hull CCG will only commission referral to a plastic surgeon if symptoms are severe, recurrent or causing significant problems and other conservative treatments have not worked. Referral is also commissioned in populations who are unlikely to benefit from steroid injections (eg. a diabetic with many digits affected and severe symptoms). Surgery involves division of the flexor sheath of the digit, either by conventional open, or percutaneous, release. This is an effective treatment with a high success rate, low complication rate and short recovery period (3-4 weeks).

		Paediatric Trigger Thumb NHS Hull CCG will commission early referral to plastic surgery for children with severe and prolonged flexion deformity or where there is diagnostic uncertainty. (Differential diagnoses include hypoplastic or clasped thumbs which require early treatment). After confirmed diagnosis, up to 78% of cases of paediatric trigger thumb resolve spontaneously, sometimes assisted by splinting and passive stretching. Where surgical release of the flexor sheath of the thumb is appropriate, it is almost always successful and usually performed as a day-case under a short general anaesthetic.
		Dupuytrens contracture Spontaneous resolution does not occur; however in general nodules do not require treatment. However if contractures are causing loss of hand function or if there has been rapid progression of the condition over a few months NHS Hull CCG will commission referral to plastic surgery for assessment and treatment. Treatment in secondary care might include Percutaneous Needle Fasciotomy (NICE IPG 43) or surgical treatment such as limited segmental fasciotomy.
	Hip	*Greater Trochanteric Pain Syndrome* The condition is usually self-limiting over weeks or months. Conservative treatments include limiting activity, applying an ice pack, a month of treatment with paracetamol or NSAIDs, weight loss if BMI >30 and up to 3 injections of steroid and local anaesthetic. Physiotherapy may help if a steroid injection does not improve symptoms. NHS Hull CCG will only commission referral to secondary care for advice and further treatment if the condition is severe or persistent. ESWT may be commissioned after IFR approval.
	Knee	*Bursitis, Tendonitis, Arthritis, Cartilage Tears and Gout.* Unless infection is suspected or present, conservative treatment includes corticosteroid injection (no more than once every three months) into the knee joint for relief of moderate to severe pain. The injection may be combined with a local anaesthetic. In osteoarthritis, pain relief may only last for up to 4 weeks. Corticosteroid injections are just one aspect of a treatment programme which may also include NSAIDs, knee exercises, knee braces and walking aids. NHS Hull CCG will only commission referral to secondary care (after an ultrasound scan) for advice and further treatment if the condition is severe or persistent. Intra-articular hyaluronic acid injections into the knee by specialist consultants in secondary care will only be commissioned, after agreement via the IFR process, in cases where it has been demonstrated that all the relevant criteria are fulfilled. [See separate commissioning policy for Hyaluronic Acid Injections.]
	Ankle	*Achilles tendinopathy* There is insufficient evidence to determine the most appropriate treatment for acute or chronic achilles tendonitis. There is no clear evidence that steroid injections are beneficial (they can weaken the tendon) but other possible treatments are analgesics, short term NSAIDs, ice, rest, increased warm-up/stretching exercises, physiotherapy and heel lifts (orthotic devices). For most people, symptoms usually clear within 3-6 months of starting treatment. NHS Hull CCG will only commission referral to secondary care if symptoms are severe or causing significant problems and other conservative treatments have

		not worked. Secondary care treatment option are ESWT (after IFR approval) or surgery. Surgery involves either removing nodules or adhesions that have developed within the damaged tendon, or making a lengthways cut in the tendon to help to stimulate healing. Complications from surgery are uncommon but can include problems with wound healing.
		Ankle impingement syndrome Conservative treatments include NSAIDs, ice packs, strengthening and stretching exercises, bracing and orthotics. NHS Hull CCG will only commission referral to an orthopaedic surgeon for assessment if symptoms are severe, causing significant problems and other treatments have not worked. Surgery usually involves using arthroscopic methods to remove the bone spur, inflamed tissue, or scar tissue.
	Heel	*Plantar fasciitis* Conservative treatments include rest, ice application, NSAIDs, stretching exercises, podiatry, orthoses or strapping, night splints or an injection of corticosteroid and local anaesthetic. (Consideration should be given to whether the injection requires ultrasound guidance, if so a referral should be made to secondary care.) NHS Hull CCG will only commission referral if symptoms are severe, recurrent or causing significant problems and other conservative treatments have not worked. ESWT may be commissioned after IFR approval.
Effective from	October 2013 *(This policy supercedes Hull PCT policy T12a/10 'Minor Surgery – Injections' dated June 2011)*	
Summary of evidence / rationale	Tendinopathy is a broad term encompassing painful conditions occurring in and around tendons in response to overuse. Recent basic science research suggests little or no inflammation is present in these conditions. Thus, traditional treatment modalities aimed at controlling inflammation such as corticosteroid injections and nonsteroidal anti-inflammatory drugs (NSAIDS) may not always be the most effective options. A systematic review of the literature to determine the best treatment options for tendinopathy concluded NSAIDS and corticosteroids appear to provide pain relief in the short term, but their effectiveness in the long term has not been demonstrated. Surgery remains the last option due to the morbidity and inconsistent outcomes. The ideal treatment for tendinopathy remains unclear. (Andrews 2008)	
Date	June 2017	
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Related NHS Hull CCG policies:

- Extracorporeal Shockwave Therapy (ESWT)
- Carpal Tunnel Syndrome (surgery)
- Ganglion (surgery)
- Hyaluronic acid injections for knee osteoarthritis

References:

1. Andrews and Murrell, 2008, Treatment of Tendinopathy: What Works, What Does Not, and What is on the Horizon. Clin Orthop Relat Res. 2008 July; 466(7): 1539–1554. http://www.ncbi.nlm.nih.gov/pubmed/18446422
2. C A Speed, Corticosteroid injections in tendon lesions. BMJ. 2001 August 18; 323(7309): 382–386 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1120980/
3. Davidson, S et al. A Primary Care Perspective on Keloids. Medscape J Med. 2009; 11(1): 18. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2654675/?tool=pubmed
4. British Society for Surgery of the Hand. BSSH Evidence for Surgical Treatment (BEST) http://www.bssh.ac.uk/education/guidelines
5. Woodward and Gellman (2013) Calcifying Tendonitis Treatment & Management http://emedicine.medscape.com/article/1267908-treatment

Useful websites:

Map of Medicine
http://nhsevidence.mapofmedicine.com/evidence/map/plantar_fasciitis2.html

nhs.uk
http://www.nhs.uk/Conditions/Frozen-shoulder/Pages/Treatment.aspx
http://www.nhs.uk/Conditions/Tennis-elbow/Pages/Treatment.aspx
http://www.nhs.uk/Conditions/heel-pain/Pages/Treatment.aspx

Patient.co.uk
http://www.patient.co.uk/health/achilles-tendinopathy
http://www.patient.co.uk/doctor/Keloid-Scars.htm
http://www.patient.co.uk/health/Greater-Trochanteric-Pain-Syndrome.htm
http://www.patient.co.uk/doctor/joint-injection-and-aspiration