NHS North Kirklees and Wakefield CCG Commissioning Policy

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Committee Approved by: NHS North Kirklees CCG Clinical Strategy Group and Wakefield CCG Clinical Cabinet

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1 Introduction

NHS North Kirklees and Wakefield Clinical Commissioning Groups (From this point forward within this document referred to as the CCGs) receive a fixed budget from Central Government. This budget is used to commission cost effective, high quality, clinically effective/evidence based healthcare that meets the requirements of the local population and delivers value for money.

All Clinical Commissioning Groups (CCGs) are required to develop, implement and monitor a Commissioning Policy. The requirement for a policy falls directly out of the NHS Constitution and the directions from the Secretary of State.

The Commissioning Policy should be clear, understandable and available to our local population, clinicians, providers of services, other commissioners and other organisations and will be published on the CCGs web sites. Written copies will also be available on request.

The policy describes the services the CCGs are responsible for commissioning. It will also make reference to specific policies where Referral Criteria, Prior Approval or Individual Funding Requests (IFR) for some conditions may apply. An evidence based approach has been adopted in the development of the Commissioning Policy and the sub policies referenced within it, in order to further improve clinical outcomes for our local population.

The CCGs undertake a strategic planning process which leads to decisions made in its annual commissioning round. The CCGs seek to take decisions about which services to commission through a systematic approach which is centred on assessing the health requirements of our local population in order that the CCGs can commission high quality cost effective services that meet these needs.

The CCGs also work in partnership with members of the Health and Wellbeing Boards which brings together local commissioners of health and social care, elected representatives, wider partners and representatives of Healthwatch to agree an integrated way to improving local health and wellbeing, reducing inequalities and improving outcomes.

The Commissioning Policy aims to support the strategic direction outlined by the CCGs and the Health and Wellbeing Boards. In this way, the Commissioning Policy supports the commissioning of services based on the needs of the population identified within the Joint Strategic Assessments (JSAs)
2 **Scope of the Policy**

Clinical Commissioning Groups (CCGs) are responsible for commissioning local healthcare services for their patients. Through partnership working across the health economy with partners including local authorities and communities, the CCGs aim to deliver local health services that are responsive to patients’ needs. This policy aims to describe the services commissioned by the CCGs.

The overwhelming majority of treatments that the CCGs commission do not require adherence to specific policies where Referral Criteria, Prior Approval or IFR approval from either CCG is required before they can start, as services are commissioned in adherence to national policy.

However, there are instances when referral criteria aren’t met or the proposed procedure/treatment is not routinely commissioned and prior or IFR approval is needed before a treatment may commence. Such instances are covered by this policy;

NHS England is responsible for commissioning, family health services of dentistry, community pharmacy and primary ophthalmic services and a number of specialist services. This policy does not cover those services commissioned by NHS England. It is recognised that the CCGs are required to oversee the care and wellbeing of the local population and therefore is intrinsically linked to supporting those services NHS England commission on their behalf of them for their registered patient population.

In relation to decisions on Prior Approval or IFR, the CCGs have a clear and transparent process and policy for decision-making to allow patients and their clinicians to be reassured that due process has been followed in the decisions made by the Prior Approval and Individual Funding Request Panels. It is paramount that due consideration is given to these requests for services or treatments which do not form part of core commissioning arrangements or need to be assessed as exceptions to the CCGs Commissioning Policy. This process must be equitably applied to all requests

**Prior Approval** – These are procedures/treatments that are routinely commissioned but have an Eligibility Criteria prior to referral. If the patient doesn’t meet the Eligibility Criteria for a referral for a certain procedure/treatment but the referring clinician opinion is that there is an exception that warrants a referral for the need of an individual patient then prior approval is required.
Individual Funding Requests - Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). However, there may be circumstances that in the Clinician opinion that there is exceptional circumstances that warrant a case for the need of an individual patient, this is when an IFR is required.

All, commissioning, Prior Approval, IFR and associated policies are publicly available on the website for:
NHS North Kirklees CCG at https://www.northkirkleesccg.nhs.uk/ And
NHS Wakefield CCG at https://www.wakefieldccg.nhs.uk/home/

Specialist services that are commissioned by NHS England or Public Health England are not included in this policy. These can be found at

http://www.england.nhs.uk/ourwork/commissioning/policies/
and
https://www.gov.uk/government/organisations/public-health-england

2.1 Aims and Objectives

The aim of this policy is to detail guidelines on how the CCGs will commission services, interventions and treatments.

To have a clear policy and process for:
- Those procedures that have Referral Eligibility Criteria Restrictions
- Have a systemic and consistent approach to the management of Prior Approval Requests
- Have a systemic and consistent approach to the management of Individual Funding Requests.
- Consider the legal aspects of priority setting

The objectives of this policy are to:
- To be compliant with the NHS Confederation guidelines on interpretation of legislation
- To have systems in place that enable a consistent approach to decision-making within appropriate timescales
- To ensure decisions made are based on the best available evidence at the time of consideration
Give clarity to our local population on what services, interventions and treatments are funded by the CCGs and under what circumstances;
Give clarity to providers of commissioned services on what services, interventions and treatments are funded by the CCGs and under what circumstance;
Give clarity to referring clinicians when there is Referral Criteria or Prior Approval is required CCGs Individual Funding Requests Team
Ensure there is equity of access to services, interventions and treatments for all the CCGs registered patient population.

2.2 Legal Context
The CCGs have a duty:
• To allocate healthcare resources, utilising a consistent framework for decision making
• To promote and provide a comprehensive healthcare service within its allocations and consider how this is best done

The CCGs need to be satisfied that any decision follows the procedures and processes described in this document and in doing so ensure requests are considered on their own merits.

The courts have established that a CCG is not under an absolute obligation to provide every treatment that a patient demands, although they must be able to clearly demonstrate why a treatment has been refused (NHS Confederation, 2008a). A CCG can develop a policy which prioritises treatment to take account of the resources available to it and the competing demands on those resources. Patients with rare or unusual medical conditions have as much right to care as anyone else and have the right to have their requests considered properly, on their own merits and against the CCGs policy in each individual case. [https://www.england.nhs.uk/wp-content/uploads/2013/03/a-functions-ccgs.pdf](https://www.england.nhs.uk/wp-content/uploads/2013/03/a-functions-ccgs.pdf)

The need for priority setting processes to be central to CCGs corporate governance in relation to Individual Funding Requests and commissioning decisions cannot be underestimated because the potential for Judicial Review is increasing. Judicial Review is the process by which the lawfulness of decision-making can be challenged and can occur as a result of major service change or refusal to fund treatments for individual patients. There are grounds for a review if:

• Decisions may be unlawful – acting outside statutory power (e.g. not following direction of Secretary of State)
• Decisions may be irrational – considering irrelevant/excluding relevant factors
• Decisions are procedurally improper – (e.g. failure to comply with the CCGs policy or the CCGs policy itself being unlawful or irrational)
(NHS confederation, 2008a)

2.3 **Commissioning Principles**
It is the responsibility of the CCGs to commission services based on the following principles:
- Achieve the greatest possible improvement in health outcome for the patient population of the CCGs within resources available;
- Prioritise healthcare interventions that produce the greatest benefits for patients in terms of both clinical improvement and improvement in quality of life;
- Services being of proven clinical effectiveness, securing the greatest possible health gain from available resources;
- Services being safe for the patient or population and offering good positive experiences for the patient and their carers;
- Keep within budget, and ensure services commissioned are cost effective to make sure that the people of Wakefield and North Kirklees obtain the optimal value from the available resources;
- Commitment to make sure that there is equitable access to services for patients within the CCGs; and
- Adherence to the CCGs [Safeguarding Children and Vulnerable Adult Commissioning Policy 2012](#) and the [Mental Capacity Act Policy 2012](#) and subsequent updated revisions of these where feasible.

CCGs have a statutory duty to provide health care for their population and in doing so have to take account of the resources available, usually a fixed budget from central government to commission health care and services. The CCGs commissioning principles are used to make decisions in a consistent, fair and transparent way, given that funds are not endless and choices inevitably need to be made. The criteria for commissioning treatments are:

- **Clinical Needs** – Consideration should be given to understanding the need and whether we are likely to achieve the greatest possible health outcome for the patient. Health care interventions which produce the greatest benefit in terms of clinical improvement and/or improvements in quality of life should be prioritised.
- **Lawful** – As previously discussed at the beginning of this policy as part of the legal responsibilities of the CCGs. In addition, as part of this process a Clinician makes a request on behalf of the patient and therefore must be aware of the
need to obtain informed consent for the referral as well as ensuring the patient is aware of both the potential benefits and risks of any treatment being requested.

- **Clinically Effective** – Commissioning decisions should be based on evidence of effectiveness wherever possible. For example, this could come from sources such as NICE, Cochrane reviews, meta-analysis or randomised control trials.

- **Cost-effective** – Given limited resources, the CCGs must receive optimum value from available resources. However it is important to note that cost alone will not be a reason for refusing an Individual Funding Request. The Exceptional Cases Committee shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the CCGs. The CCG is however required to bear in mind that the allocation of any resources to support any individual patient will reduce the availability of resources for investments in previously agreed care and treatments.

- **Equitable** – In this context equity means that if an Individual Funding Request is agreed for a new treatment/drug trial then it could lead to service development which could benefit the wider population. In addition, once a precedent has been set, it is likely that future requests for the same treatment would also qualify for funding, subject to the clinical presentation of the patient.

- **Accessible** - While accessibility implies utilisation of local services the CCGs also need to take into account patient choice. The CCGs would expect referrals to be made to the NHS services wherever possible but a choice list will be provided to highlight where the CCGs will fund treatment outside the local NHS if available and where requested by the patient.

- **Good quality of care and patient experience** – Decisions should be based on the potential to deliver good and safe care, improve health outcomes and enhance patient experiences. Individual Funding Requests should be agreed if it meets this criterion and will achieve or has the potential to achieve explicit measures of quality, including:
  1. Patient feedback through local and national surveys, PALS and complaints
  2. Local and national standards, targets and quality indicators

### 2.4 Application of the Policy

The commissioning decisions described in this policy and supporting policies and documents referred to within it, apply to all staff (clinical and non-clinical) who are involved in any way with the commissioning, authorising of treatments or proposed clinical interventions commissioned by the CCGs.
This policy must be followed by all staff who are employed by the CCGs including those on temporary, fixed-term or honorary contracts, secondments, pool staff and students. It must also be followed by any organisation contracted to commission, authorise or administer healthcare on behalf of the CCGs. Both referrers (including GP practices) and provider organisations are expected to adhere to the principles, criteria and policies set out in this document. Any service requested or provided outside of the funding criteria set out in this policy will be undertaken at the organisations’ own risk.

2.5 Screening and Decision-making Principles

The screening panel will assess each individual request taking into account:

Appropriateness, comprehensiveness, effectiveness (including that of safety), size of intended benefit (outcomes), alternative interventions and consequences of not having the treatment / intervention.

Individuals requesting funding are screened for:
- Whether the CCG or NHS England are the responsible commissioner.
- Treatment or drugs not covered by existing Service Level Agreements or are specifically identified as exceptions within the Service Level Agreement
- Treatment availability locally but requested from another provider where additional costs will lead to uncertain extra clinical benefit
- Treatments or drugs that are not routinely commissioned
- Treatment or drugs that are new or experimental
- Complex or unusual cases

The following guidance should also be taken into account when considering appropriateness of a request:

High Cost Drugs: Individual Funding Requests for high cost drugs. On receiving a request for high cost drug treatment the screening panel will consider available evidence based reviews to inform the decision-making process. The request will also be reviewed by a Medicines Management Representative to provide key information that should be considered. A representative from Medicines Management will attend the screening panel to present any information and discuss these cases as required.

Introduction of New Drugs or Treatments: Consideration of new drugs/treatments should be referred into established planning frameworks but a decision should be made as to whether an interim commissioning policy is needed to enable the
clinician/patient to access treatment.

**Restricted Treatments:** Treatments not included in existing pathways are not routinely funded but policy statements on restricted treatments are available. Individual Funding Requests can be considered in relation to these restricted treatments to assess whether the request fits the criteria or if exceptional circumstances exist.

**Rare Conditions:** NHS England has the responsibility for commissioning treatments for many rare conditions as set out in the Specialised Services Manual and accompanying documents. The CCG will be the responsible commissioner where NHS England is not responsible for commissioning the service. These patients are unlikely to have treatment options covered by NICE guidance or commissioning policies and therefore, Individual Funding Requests should be considered against the commissioning principles.

**Drug Trials:** The CCGs will not usually provide funding for individuals coming off drug trials unless prior agreement has been obtained before commencement of the trial. In accordance with the Medicines Act (2004) responsibility for an exit strategy from a trial lies with those conducting it (NHS Confederation, 2008b).

**Continuing Private Care:** Funding for individuals to continue care purchased privately, where an individual has exhausted their own resources or chosen to terminate a private arrangement, will not routinely be funded by the CCGs. Applications for funding can be considered via the funding request process in the usual way.

**Inheriting decisions from other PCTs / CCGs:** Patients moving into either of the CCG areas and registering with a GP in that CCG area, become the responsibility of that CCG and therefore decisions for treatment already agreed by the previous PCT / CCG would normally be upheld as long as it is consistent with the principles in this policy and the Department of Health publication “Establishing a Responsible Commissioner”.

**Retrospective Payment:** The CCGs would not support applications for patients who have paid for private treatment and then ask for reimbursement of these costs from the CCG because prior approval for funding should have been sought through the processes outlined in this policy.

**Co-payment:** Patients who pay for some aspects of treatment while being treated in the Public Sector. The NHS Act (2006) does not allow for recovery of charges for healthcare and the Code of Conduct for Private Practice: Guidance for NHS Medical Staff (2003) states that patients wishing to become private patients cannot be treated as both a private and NHS patient during the same visit to an NHS Organisation. The government’s current position is to rule out co-payment and it is recommended that CCGs follow this guidance because it would provide access to a treatment that the CCGs were not making available to others (NHS Confederation,
2008b).

Patient Safety: The CCGs have a responsibility for patient safety when being treated in healthcare settings. The Care Quality Commission (CQC) governs the suitability of providers of NHS services and therefore patients should only be referred to providers registered with the CQC.

Exceptionality: Exceptionality should be considered in the context of the CCGs general policy for an intervention and specified indication.

In general, the CCGs must justify the grounds upon which they are choosing to fund treatment for a patient when the treatment is unavailable to others with the condition.

A patient may be considered exceptional to the general policy if:

• The patient has demonstrated exceptional clinical circumstances in comparison to the cohort of other patients in the same clinical condition1 (Patient is significantly different to the general population of patients with the condition in question who would normally be refused treatment)
• It is likely that the requested treatment will be clinically effective (there are good grounds to believe the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition. e.g. may not tolerate standard treatment options.

When considering Prior Approval or Individual Funding Requests the CCGs will use the same ethical framework and guidelines for decision-making that underpin its general policies for health care interventions, see commissioning principles above. Where social, demographic or employment circumstances are not considered relevant to population based decisions, these factors will not be considered for Prior Approval or Individual Funding Requests. Any assessment of exceptionally will therefore be based primarily on the consideration of clinical need.

When a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage not disadvantage the patient. Response to an intervention will not be considered to be an exceptional factor.

Though this test may need some revision in the case of a patient with a rare condition where there is no policy

Procedures
A Prior Approval or Individual Funding Request is a request to a CCG to fund healthcare for an individual who doesn’t meet the Eligibility Criteria for a referral or falls outside the range of services and treatments that the CCG has agreed to commission (NHS Confederation 2008b). The process should be both thorough and comprehensive taking into account the legal issues and commissioning principles outlined in the policy above.

The process of decision making in all cases should therefore be:
• Consistent – in line with agreed policy
• Concise – often requests for funding are related to care which is required relatively urgently, but not so concise that key issues are marginalised
• Transparent and explicable
• Defensible – based on sound evidence from national or legal guidance

2.6 The Prior Approval Funding Requests Procedure

The Prior Approval Funding Request procedure can only be initiated by a clinician i.e. the General Practitioner, Consultant or Dentist making a request for funding for a treatment to the CCG. It is the responsibility of the individual seeking funding in conjunction with the referring clinician to ensure that all relevant information is forwarded to the CCG. This should include:
1. An outline of the patient’s problem and the circumstances of the case, including any previous treatment
2. A clear statement of the referral/treatment plan proposed
3. Consideration of whether the patient’s needs could be met within existing pathways
4. If the care could be provided within existing pathways, a statement of why an alternative referral, which would not be offered to others with a similar clinical need, is a priority in this case

A Prior Approval Funding Request Form (Appendix 2) should be completed by the referring clinician in all cases in order to ensure all the above information is received.

The only exception to this is when an alternative proforma is available from individual Trusts requesting high cost drugs for individual patients.

If a referral form is not completed the referral will not be considered until the CCG has received the information that they require to enable a decision to be made.
All requests for funding should be referred in writing, preferably typed, in the first instance to the IFR Team. All requests must be legible in order to avoid delays in consideration of the request.

The completed form should be sent to NHS Greater Huddersfield CCG IFR Team:

IFR Manager
Individual Funding Requests Team
NHS Greater Huddersfield Clinical Commissioning Group (GHCCG)
Broad Lea House
Bradley Business Park
Dyson Wood Way
Bradley
Huddersfield
HD2 1GZ

Telephone: 01484 464438
Email: GHCCG.IFR-CKW@nhs.net.
Safe Haven Fax: 01484 464062

There will be three stages for considering Prior Approval

Screening Panel

IFR Panel (WCCG) or Exceptional Cases Committee (NKCCG)

Appeals Committee

2.7 The Individual Funding Requests Process

NHS North Kirklees and NHS Wakefield CCGs currently have a slightly different process for The Individual Funding Requests Procedure

Please refer to Appendices:

Appendix 3 - NHS North Kirklees CCG IFR Process
3 Accountability and Monitoring

Accountability and Responsibilities
The Chief Officer and Governing Body of the CCGs are accountable for the discharge of CCG statutory duties and have a scheme of delegation in place that is set out in the CCGs standing orders and standing financial instructions.

CCG Leads
The Lead Manager with overall responsibility for this policy and the procedures within it is the CCGs Chief Operating Officers, the CCGs Joint Planned Care Lead and the CCGs Clinical Leads (via Clinical Strategy Group NKCCG and Clinical Cabinet WCCG)

Committee Accountability
Overall responsibility for the development and implementation of this policy and its procedures remain with each CCGs Governing Body. There is an annual (NKCCG) and 6monthly (WCCG) report which is made available to the Quality, Performance and Finance Committees (NKCCG) and Integrated Governance Committee (ICG) (WCCG) and reported formally to the Governing Bodies of each CCG to enable them to:
• Ensure the systems in place are sufficient to meet patients’ needs
• Ensure that decisions made throughout the process are consistent and appropriate
• Ensure positive health outcomes are being achieved as a result of the decisions made.

Delegated Responsibilities
Greater Huddersfield CCG is the host commissioner for the implementation of the Prior Approval and Individual Funding Requests process on behalf of the CCGs. (The dedicated team responsible for the screening of requests sits within this organisation). Responsibility for decision making regarding Individual Funding Requests on behalf of the CCGs has been delegated by the Governing Bodies of each CCG to:

• The Joint Exceptional Cases Committee (ECC) - There is a Joint ECC for NHS Greater Huddersfield and NHS North Kirklees CCGs
The IFR Panel for Wakefield CCG

The membership, roles and responsibilities of each of these bodies is set out in the Screening and Decision-Making Principles section of this document.

Responsibility for Policy Review
The CCGs formal Clinical decision-making forums are responsible for the formal approval and ratification of the policy on an annual basis to ensure continued relevance and applicability to the 5-year vision. An evidence base approach to reviewing all clinical policies referenced within the Commissioning Policy will be adopted. The review will include reference to national guidance, the commissioning approaches adopted by other CCGs and reflect the findings from the local Joint Strategic Assessments (JSAs). Therefore, this policy (and the associated policies listed within it) may be superseded.

The formal Clinical Decision-making forums are also responsible for recommending the approval of newly developed evidence based commissioning policies and eligibility criteria for specific procedures on an ongoing basis. Those policies, agreed by the formal Clinical Decision-making forums, will be incorporated into the Commissioning Policy.

When a policy decision needs to be made, recommendations will go to;
For NKCCG:
- Senior Management Team – for decisions involving policy changes that impact on the management of the CCGs
- Quality & Safety Committees – for clinical decisions
- Finance & Performance Committee – for financial impacts
- Governing Body

For WCCG:
- Executive Team – for decisions involving policy changes that impact on the management of the CCGs
- Clinical Cabinet – for clinical decisions
- Integrated Governance Committee
- Governing Body

Commissioners will monitor adherence to this policy through the contracts they hold with providers and also through their Prior Approval and Individual Funding Request process.
4 Equality and Quality Impact Assessments

The CCGs aim to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. This policy is not intended to discriminate against any group or individual on the grounds of ethnicity, gender, age, disability, sexual orientation or religion/belief. The Commissioning Policy Equality and Quality Impact assessment will be carried out for this policy. Where North of England Specialised Commissioning Group (NESC) has developed policies, their Equality and/or Quality Impact Assessments will apply.

5 Implementation and Dissemination

As part of the annual review and implementation process, this document will be shared with the CCGs Locality Networks, the Local Medical Committees (LMCs), Local Optical Committees, the Local Authorities, Mid-Yorkshire Hospitals NHS Trust and all other service providers directly commissioned by the CCGs.

This policy will be disseminated via the CCGs intranet and website. Written copies will be made available to any member of the public on request via the Patient Advice and Liaison Service (PALS): -

For NHS Kirklees CCG:
You can contact PALS by email to PALS-NKCCG@northkirkleesccg.nhs.uk
Telephone: 01924 504975 (with confidential answer phone)

If you prefer to write:
PALS
NHS North Kirklees Clinical Commissioning Group
4th Floor, Empire House
Old Wakefield Road
Dewsbury
WF12 8DJ
https://www.northkirkleesccg.nhs.uk/health-services/patient-advice-and-liaison-service-pals/

For NHS Wakefield CCG:
You can contact PALS by email to EMBED.PALS@nhs.net
Telephone: 0800 0525 270 (Mon – Fri: 8.30am to 4.30pm)
6 The CCGs Commissioned Services

The Health and Social Care Act (2012) and the governments paper 'Equity and Excellence: Liberating the NHS', 2010) describe the changes to the structure of the NHS and commissioning responsibilities of the new organisations (Clinical Commissioning Groups and NHS England) which came in to place from the 1st April 2013.

The paper ‘The Functions of Clinical Commissioning Groups’ (2012) details the services CCGs are responsible for commissioning, these being:

‘CCGs will be responsible for commissioning healthcare services to meet the reasonable needs of the persons for whom they are responsible (i.e. principally for patients registered with their member practices, together with any unregistered patients living in their area), except for those services that the NHS Commissioning Board (now NHS England) or local authorities are responsible for commissioning. This will include, but will not necessarily be limited to:

- Community health services
- Maternity services
- Elective hospital care
- Rehabilitation services
- Urgent and emergency care including A&E, ambulance and out-of-hours services
- Older people’s healthcare services
- Healthcare services for children
- Healthcare services for people with mental health conditions
- Healthcare services for people with learning disabilities
- Continuing healthcare
- Abortion services
- Infertility services
- Wheelchair services
- Home oxygen services
- Treatment of infectious diseases

CCGs will also be responsible for meeting the costs of prescriptions written by their members’ practices, but not the associated dispensing fees.’

The overwhelming majority of treatments which the CCGs commission do not require the prior approval of the CCGs before they can start, as services are commissioned in adherence to national policy. However, there are instances when the prior approval of the CCGs is needed before a treatment may commence. Such instances are of an exceptional nature and covered by this policy; see section 10 Services and Interventions with Eligibility Criteria.

Services commissioned by CCGs and NHS England are summarised in Appendix 1.

7 NHS England Commissioned Services

The Health and Social Care Act (2012) also established a new board to oversee the functioning of the CCGs, to improve the health outcomes of the public and to directly commission some services. This board is now known as NHS England. This section summarises the services which NHS England directly commission.

7.1 Primary Care, Offender Health and Armed Forces Health Services

NHS England is responsible for direct commissioning of services outside the remit of clinical commissioning groups, namely, public health, offender health, military and veteran health and specialised services.

NHS England is responsible for the commissioning of secondary care and community services for serving personnel and their families registered with a Defence Medical Services (DMS) practice and mobilised reservists. The Ministry of Defence (MoD) will continue to provide GP, dental and some specialist community services for serving personnel and GP services for those families registered with a DMS practice. CCGs are responsible for commissioning all health services for reservists (when not mobilised), veterans and families not registered with a DMS practice.
NHS England is also responsible for commissioning directly health services or facilities for people who are detained in prison or in other secure accommodation and for victims of sexual assault.

### 7.2 NHS England Commissioned Specialised Services

NHS England is also responsible for the commissioning of specialised and highly specialist services that help improve the lives of children and adults with rare diseases or disorders.

Specialised Services are those provided in relatively few hospitals, accessed by comparatively small numbers of patients but with catchment populations of more than one million. These services tend to be located in specialist hospital trusts that can recruit staff with the appropriate expertise and enable them to develop their skills.

NHS England Specialised Services produce commissioning policy with respect to Specialised Services covered by the national definitions set. Four factors will determine whether a service is commissioned as a Specialised Service, as follows:

- The number of individuals who require the service;
- The cost of providing the service or facility;
- The number of people able to provide the service or facility and
- The financial implications for CCGs if they were required to arrange for provision of the service or facility themselves.

There are currently 143 prescribed specialised services. The [Manual for Prescribed Services](https://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf) (NHS England) details each of the 143 services and a rationale as to why a service is commissioned by NHS England and not by CCGs.

The CCGs are committed to commission in line with policies developed and agreed through NHS England Specialised Services. These are important in clearly defining what NHS England expects to be in place for providers to offer evidence-based, safe and effective services and importantly, sets equitable access to services across the country. The policies were initially developed by specialised clinicians, expert patients and Public Health representatives, working together in Clinical Reference Groups, before being put out for consultation during late 2012/early 2013.
Where the NHS England Specialised Services has ‘endorsed’ proposed policies or produced guidance rather than policy; The CCGs will endeavour where possible to commission in line with the guidance where it relates to services, treatments or interventions that have been identified as local priorities.

There are also NHS England policies available for the services which they commission, accessed through the following link; http://www.england.nhs.uk/policies/

7.3 Cancer Drugs Policies and Funding

From 1st April 2013 NHS England will commission specialist cancer drugs and are therefore responsible for the associated policies and specialist cancer drug funds.

8 Guidance which Informs Commissioning Decisions

Adopting an evidence based approach, the CCGs will make reference to national guidance to inform our commissioning decisions.

8.1 National Institute of Clinical Excellence (NICE)

The National Institute of Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health, prevention and treating ill health.

8.1a NICE Clinical Guidelines

NICE publish clinical guidelines which are recommendations on the appropriate treatment and care of people with specific diseases or conditions. They are based on the best available evidence. Whilst clinical guidelines help health professionals in their work, they do not replace their knowledge and skills.

The CCGs are not obligated to automatically commission services in line with this guidance. However, such guidance will improve clinical effectiveness of services (a guiding principle indicated previously), therefore where it relates to services, treatments or interventions that have been identified as a national or local priority then the CCGs will endeavour to commission in line with NICE clinical guidance.
8.1b NICE Technology Appraisal Guidance (TAG)

NICE Technology Appraisal Guidance (TAG) provides recommendations on the use of new and existing medicines, devices and treatments. Their aim is to standardise the availability of a particular drug or treatment across the country. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE technology appraisals.

There are currently no exceptions to NICE Technology Appraisals. The commissioning statements for all current Technology Appraisals are available on the CCGs website.

A clinician or patient can take it that a service, intervention or treatment is funded in line with NICE criteria and guidance if:

- there is no exception or local policy indicated and;
- a period of three or more months has elapsed since publication of a TAG.

8.2 Department of Health (DH) Clinical Guidelines

Like NICE, the Department of Health regularly produce clinical guidelines suggesting best practice. These are also considered when commissioning services in line with other guidance available.

8.3 Other Published Guidance

Other guidance and evidence produced also informs our commissioning decisions. Public Health undertakes local needs assessments and produces guidance based on national recommendations in conjunction with local interpretation. This informs the commissioning of local services.

The Scottish Intercollegiate Guidelines Network (SIGN) produce evidence-based clinical practice guidelines which are derived from a systematic review of evidence. These ‘are designed as a vehicle for accelerating the translation of new knowledge into action to meet our aim of reducing variations in practice, and improving patient-important outcome,’ (SIGN, 2013).

Other publications may be used to ensure commissioning decisions are evidence based including professional bodies for clinicians (e.g. royal colleges) and scientific literature. Documents will be reviewed and validated prior to accepting its proposals in commissioning services.
9 **Choice**

Choice is a department of health initiative approach to healthcare which when appropriate aims to give patients greater control over what healthcare they receive, where and when. The CCGs will commission services in line with the national choice agenda. Each CCG has a NHS Choice Framework which is a guide to your choices about your NHS care and treatment.

These can be accessed on the Individual CCGs Websites
NHS North Kirklees CCG at [https://www.northkirkleesccg.nhs.uk/](https://www.northkirkleesccg.nhs.uk/)
And
NHS Wakefield CCG at [https://www.wakefieldccg.nhs.uk/home/](https://www.wakefieldccg.nhs.uk/home/)

The framework explains:
- When you have choices about your healthcare
- Where to get more information to help you choose
- How to complain if you are not offered a choice

Further information is available at [NHS Choices website](https://www.nhsexplorewellbeing.nhs.uk/choices/)

Choice is available to the CCGs commissioned consultant led outpatient services. The e-Referral service (previously known as Choose and Book system will describe to patients where they can choose to receive a service, for which their GP has referred them. Local GPs should be aware of services not available on the e-Referral service via Local Clinical Networks and direct communication from the CCGs. Wherever possible, providers should be encouraged to use the e-Referral service.

Choice does not mean a patient can change the CCGs commissioning policy by seeking to extend the range of treatments or providers commissioned. The offer of choice may need to be adapted to meet a number of circumstances including (but not limited to) the requirement to provide specialist services, in order to maintain efficient and effective supply or where are problems matching supply and demand, to ensure value for money and affordability and to ensure high quality services are delivered to patients.

Choice is not available for some commissioned services. For example, these arrangements do not apply to Continuing Care, Continuing Healthcare and Funded Nursing Care patients (these specific examples are described elsewhere
in this document), services for people detained under the Mental Health Act 1983 (Updated 1 April 2015) some cancer services and any person detained in prison.

If a patient or GP is in any doubt about the availability of a provider/service then they can seek advice from Patient Advice and Liaison Service (PALS). Details as above in Section 5 (page14)

10 Services and Interventions with Eligibility Criteria
For some services, eligibility criteria apply. This section refers to this group of services, interventions and treatments.

Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, they will 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 via the CCGs Prior Approval Funding Request Process. (As referred to in Section 2)

10.1 Procedures that have Referral Eligibility Criteria:
10.1.1 - Varicose Veins and Thread Veins
10.1.2 - Diagnostic Fibreoptic Endoscopic Examination for Rectal Bleeding
10.1.3 - Knee Arthroscopy
10.1.4 - Knee Replacement
10.1.5 - Hip Arthroscopy
10.1.6 - Hip Replacement
10.1.7 - Shoulder Arthroscopy
10.1.8 - Spinal Stimulation
10.1.9 - Hallux Valgus
10.1.10 - Dupuytren’s Contracture
10.1.11 - Carpal Tunnel
10.1.12 - Tonsillectomy (revised)
10.1.13 - Myringotomy with/without Grommets
10.1.14 - Hysterectomy for Menorrhagia for Heavy Menstrual Bleeding
10.1.15 - Dilatation & Curettage/ Hysteroscopy (for Heavy Menstrual Bleeding)
10.1.16 - Cataract Surgery
10.1.17 - Hernia Surgery
10.1.18 - Haemorrhoids
10.1.19 - Upright/Open MRI Scan
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<td>PROCEDURE/TREATMENT</td>
<td>10.1.1 - VARICOSE VEINS AND THREAD VEINS OSCAR REF: PA1 05/2017</td>
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**Definition**
Tortuous, superficial veins resulting from faulty valves which allows reverse venous blood flow, with subsequent venous pooling and distension in the lower leg. Causes include obesity, occupation, pregnancy and age.

**EXCLUSIONS**
Exclude Red Flag Symptoms
Deep vein thrombosis (DVT) should be excluded in any patient presenting with a red, hot swollen leg with use of the Well's criteria and d-dimer testing. Superficial vein thrombosis above the knee should be discussed with the vascular team as admission is sometimes indicated for high tie and/or anticoagulation as there is a significant potential for clot migration and PE. Bleeding varicose vein which has caused significant blood loss and/or will not stop with direct pressure may require admission.

**ELIGIBILTY CRITERIA**
NICE has issued a clinical guideline on the management of varicose veins (CG168, July 2013). This policy statement is broadly consistent with criteria for referral recommended by NICE with the exception that referral for patients with symptomatic primary or symptomatic recurrent varicose veins without complications is not routinely commissioned.

Conservative management is the first line of treatment and applications will not normally be accepted without evidence that conservative management of asymptomatic and symptomatic varicose veins has been tried, and failed, for a period of at least six months.

Unless an exceptional case is presented, the CCGs will not fund Secondary Care for the treatment of:
- Grade 0: Thread/Flare/Reticular veins
- Grade I: Varicose veins without symptoms
- Grade II: Varicose veins with symptoms such as pain, aching, heaviness or swelling

The CCGs will fund specialist advice and surgery if appropriate for the following:
- Grade III: Varicose Veins with complications, including bleeding, recurrent phlebitis or eczema
- Grade IV: Signs of venous insufficiency – lipodermatosclerosis or healed Ulceration
- Grade V: Active leg ulceration
To receive exceptional funding, a clinical advocate for the patient needs to be able to demonstrate that the patient is:

- significantly different to the general population of patients with the condition in question
- Is likely to gain significantly more health benefit from the intervention that might be normally expected for patients with that condition.

**Note:**

- Varicose veins surgery in pregnancy are not routinely commissioned and would require IFR approval.
- Consideration of exceptional circumstances will be via the Individual Funding Request Panel. For an application for consideration of funding by the Independent Funding Request Panel
- the presence of telangiectasia and reticular veins do not meet the criteria for referral.

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

**Summary of evidence / rationale**

NICE states the following:

“People with varicose veins that are causing symptoms or problems such as bleeding, eczema or leg ulcers should be referred to a specialist vascular service”

Links listed below in Reference section:
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<td>April 2018 or when new NICE Guidance is available</td>
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<tr>
<td><strong>Author</strong></td>
<td>Interim Planned Care Lead, NHS North Kirklees &amp; NHS Wakefield CCG</td>
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| **Clinical Reviewers** | GP NHS North Kirklees CCG  
Consultant Surgeon, Mid Yorkshire Hospital Trust |
| **Approved by**        | Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG) |
| **Responsible Officers** | Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
3. Patient Info - Superficial Thrombophlebitis - [http://www.patient.co.uk/health/Phlebitis.htm](http://www.patient.co.uk/health/Phlebitis.htm)  
4. Gp Notebook - Varicose Veins  
[https://www.gpnotebook.co.uk/simplepage.cfm?ID=1301938199](https://www.gpnotebook.co.uk/simplepage.cfm?ID=1301938199)  
[https://www.nice.org.uk/guidance/ipg440](https://www.nice.org.uk/guidance/ipg440)  
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<td>PROCEDURE /TREATMENT</td>
<td>10.1.2 - DIAGNOSTIC FIBREOPTIC ENDOSCOPIC EXAMINATION FOR RECTAL BLEEDING - UNDER 45 YEARS</td>
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| EXCLUSIONS       | • Patients with HIV who have an increased risk of anal cancer, emergency care patients with suspected cancer  
• Patients under the age of 45 years with any of the following symptoms over a period of six weeks should be urgently and appropriately investigated:  
  o rectal bleeding with a change in bowel habit to looseness or increased frequency  
  o rectal bleeding without anal symptoms  
  o palpable abdominal or rectal mass  
  o intestinal obstruction.  
• All patients with iron-deficiency anaemia (Hb<11g/dl in men or<10g/dl in postmenopausal women) without overt cause should be thoroughly investigated for colorectal cancer. Source: SIGN 67 (2003). |
| ELIGIBILITY CRITERIA | Diagnostic fibreoptic endoscopic examination of the colon, and diagnostic fibreoptic sigmoidoscope examination of the lower bowel with or without biopsy are NOT routinely commissioned where patients are under 45 years of age |
| Note: Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process (Appendix 2 - Prior Approval Funding Request Form) |
| NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated) | • Obesity - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.  
• Smoking - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing. |
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<td>10.1.3 - KNEE DEBRIDEMENT AND WASHOUT FOR OSTEOARTHRITIS (KNEE ARTHROSCOPY) OSCAR REF: PA3 05/2017</td>
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Knee arthroscopy is a surgical procedure for inspection and treatment of problems arising in the knee joint such as inflammation or an injury. It can include repair or removal of any damaged tissue or cartilage. It has been used extensively in the past to diagnose knee problems but this is no longer appropriate due to the invasive nature of the procedure and the increasing access to less invasive diagnostic methods such as MRI.

It is important to ensure that the evidence base is robust so that patients are not exposed to the risks without good evidence of benefit. It is important for the NHS to optimise the safety and cost-effectiveness of procedures to ensure maximum benefit for the risks and costs involved. The figures suggest that this could represent an area of improvement in cost-effectiveness and possible cost saving.

The most recent Royal College of Surgeons commissioning guide states that knee arthroscopy, lavage and debridement should NOT be offered to patients with non-mechanical symptoms of pain and stiffness. This approach is supported by many CCGs in England, including ones local to Vale of York, which do not support the routine funding of diagnostic knee arthroscopy.

**EXCLUSIONS**

Red flag symptoms or signs include recent trauma, constant progressive non-mechanical pain (particularly at night), previous history of cancer, long term oral steroid use, history of drug abuse or HIV, fever, being systematically unwell, recent unexplained weight loss, persistent severe restriction of joint movement, widespread neurological changes, and structural deformity.

Red flag conditions include infection, carcinoma, nerve root impingement, bony fracture and avascular necrosis.

**ELIGIBILITY CRITERIA**

Knee arthroscopy in secondary care is commissioned on a restricted basis. Cases will only be funded if they meet the criteria below:

Arthroscopy of the knee can be undertaken where a competent clinical examination (or MRI scan if there is diagnostic uncertainty or red flag symptoms/signs/conditions) has demonstrated clear evidence of an internal joint derangement (meniscal tear, ligament rupture or loose body) and where conservative treatment has failed or where it is clear that conservative treatment will not be effective.

Knee arthroscopy can therefore be carried out for:
- Removal of loose body
- Meniscal repair or resection / repair of chondral defects
- Ligament reconstruction/repair (including lateral release)
- Synovectomy / symptomatic plica
- To assist selection of appropriate patients for uni-compartmental knee replacement

Knee arthroscopy should NOT be carried out for any of the following indications:
- Investigation of knee pain (MRI is a less invasive alternative for the investigation of knee pain)
- Treatment of osteoarthritis including arthroscopic lavage and debridement.

In line with NICE guidance CG177; this should not be offered as part of treatment for osteoarthritis unless the individual has knee osteoarthritis with a clear history of mechanical locking (not gelling, ‘giving way’)

In rare circumstances, intractable knee pain may benefit from arthroscopic treatment (subject to agreement by exceptional cases panel Prior Approval).

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

**Summary of evidence / rationale**

For patients with non-traumatic knee injury, evidence shows that, on average, conservative treatment is as effective as arthroscopic knee surgery for some procedures. As long ago as 2002, a controlled trial addressing knee arthroscopy,
using placebo or “sham” surgery as a comparator, showed no benefit.

Partial meniscectomy surgery showed no advantage over sham in one RCT of patients aged 35-65 years with degenerative meniscal tears without osteoarthritis and no advantage over physical therapy in two RCTs of older patients (>45 years) with osteoarthritis. In a systematic review of RCTs of young patients (mean age ~20 years) with a first occurrence of patellar dislocation, there was no conclusive advantage of surgical treatments compared with non-surgical treatments. In an RCT of patients with patellarfemoral pain syndrome (18-40 years), mixed arthroscopic procedures and exercise resulted in equivalent improvements compared with exercise alone.

Although rates of post-operative complications are generally low higher rates have been observed in children and young people. There may also be future knee damage associated with arthroscopic procedures and a recent meta-analysis showed that the small benefit from arthroscopic knee surgery seen in middle aged or older patients with knee pain and degenerative knee disease was absent one to two years after surgery and was associated with an increase in significant harms such as deep vein thrombosis, pulmonary embolism, infection and death.

The paper concludes:

“The small inconsequential benefit seen from interventions that include arthroscopy for the degenerative knee is limited in time and absent at one to two years after surgery. Knee arthroscopy is associated with harms. Taken together, these findings do not support the practice of arthroscopic surgery for middle aged or older patients with knee pain with or without signs of osteoarthritis.”

Regarding knee arthroscopy, it states that lavage and debridement should be considered in patients:

- With clear history of mechanical symptoms e.g. locking that have not responded to at least 3 months of non-surgical treatment
- Where a detailed understanding of the degree of compartment damage within the knee is required, above that demonstrated by imaging, when considering patients for certain surgical interventions (e.g. high tibial osteotomy)

The RCS/BOA guidance also states (in line with NICE guidance) that “Knee arthroscopy, lavage and debridement should NOT be offered for patient with non-mechanical symptoms of pain and stiffness.”

More recently, the BMJ has published two editorials about arthroscopic surgery.
for degenerative knee or knee pain\textsuperscript{16, 17}. They both explore the evidence for benefit and harm and point out that, although this is one of the most common surgical procedures, there is no convincing evidence for the procedure being beneficial beyond the placebo effect.

A series of rigorous trials summarised in two recent systematic reviews and meta-analyses provide clear evidence that arthroscopic knee surgery offers little benefit for most patients with knee pain\textsuperscript{14, 18}.

The most recent linked paper is a comparison between exercise therapy alone and arthroscopic partial meniscectomy alone (without any postoperative rehabilitation) in adults with a degenerative meniscal tear\textsuperscript{19}. The authors found no between group differences in patient reported knee function at the two-year follow-up, but greater muscle strength in the exercise group at three months.

Over time, the indications have extended from locked knees in young patients to all patients of all ages with knee pain and meniscus tears of any sort; tears which, on magnetic resonance imaging, have proved poorly associated with symptoms\textsuperscript{20}.

Essentially, the editorials say, good evidence has been widely ignored. The most recent editorial comments that arthroscopic surgery for knee pain continues unabated, as disinvestments in ineffective treatments are generally slow\textsuperscript{17, 21}. It calls for local commissioners to respond appropriately to the evidence, because “system level measures that result in more appropriate use of scarce medical resources are urgently required”.

In addition, it says that “in a world of increasing awareness of constrained resources and epidemic medical waste, what we should not do is (…) ignore the results of rigorous trials and allow continuing widespread use of procedures for which there has never been compelling evidence”.

Rationale for up to 12 months of conservative treatment in chronic knee pain
This policy therefore specifies that conservative treatment should primarily be used but, when this fails, referral for surgery is an option. In the trial of meniscal surgery compared with conservative treatment in patients without osteoarthritis, at earlier time points, outcomes favoured surgery, but by 12 months of conservative treatment, outcomes were equivalent\textsuperscript{5}. Therefore, to allow sufficient time for benefits of conservative treatment to be gained, and to allow for any potential natural healing of joint derangements, a minimum 12 months’ restriction has been selected for which conservative treatment should be attempted before any referral.

In this trial, cross-over from the conservative group to surgery over 12 months
was low (7%). However, in other trials cross-over has been higher (around 30%)\textsuperscript{5,6} suggesting that some patients will require more urgent surgery. There may be some cases where symptoms re-occur on conservative management and these patients may benefit from surgery\textsuperscript{15}. Therefore, this policy allows for patients with mechanical locking or worsening symptoms to be referred before the 12-month period of conservative management.

**Restricted procedures**

For some interventions, the evidence identifies a lack of effect or there is insufficient evidence to warrant their use. There is currently no NICE guidance on the use of many procedures but, for the procedures that have been assessed, those not recommended by NICE will not be funded without IFR approval.

There is evidence (including from a Cochrane systematic review) that lavage does not improve patient outcome compared to sham\textsuperscript{2, 3, 24, 25, 26} and NICE does not recommend lavage\textsuperscript{2}. NICE recommends knee meniscus replacement with biodegradable scaffold only with special arrangements for clinical governance, consent and audit or research\textsuperscript{27}. NICE currently recommends that mosaicplasty should not be used without special arrangements for consent and audit or research\textsuperscript{28}.

NICE does not currently recommend autologous chondrocyte implantation for the treatment of articular cartilage defects of the knee joint except in the context of on-going or new clinical studies\textsuperscript{29}. NICE recommends arthroscopic trochleoplasty for patellar instability should only be used with special arrangements for clinical governance, consent and audit or research\textsuperscript{30}. There is some evidence that debridement is ineffective\textsuperscript{3, 24, 25}, but NICE recommends that debridement may be appropriate in cases where there is mechanical locking\textsuperscript{3}.

**Restricted use of MRI**

MRI is a good diagnostic tool\textsuperscript{22}, but may be inaccurate when used by less experienced staff\textsuperscript{23} and its use is, therefore, restricted to secondary care or specialists working in CCG commissioned MSK services for this indication.

Adapted (and updated) from evidence review in Knee arthroscopy for chronic knee pain Cambridgeshire and Peterborough CCG\textsuperscript{31}, with thanks to Dr Raj Lakshman, Consultant Lead in Healthcare

**Shared decision-making**

A letter following the recent BMJ editorial suggests that the overtreatment of knee pain with arthroscopy could be solved through the use of shared decision making\textsuperscript{32}. The NHS/BMJ aid for knee arthritis clearly states that arthroscopy for lavage and/or debridement doesn't make much difference to pain, increase
mobility around or stop symptom progression. The British Orthopaedic Association recently claimed that GPs were over-diagnosing patients with non-arthritic complaints and referring them on for surgery (instead of prescribing exercise) with the expectation that the keyhole procedure would ‘cure’ the problem, so that too many patients were undergoing needless arthroscopy. Easy access to MRI is also likely to be leading to over diagnosis of meniscal tears and subsequent overtreatment.

“Shared decision-making for the management of knee pain should begin in the GP surgery and continue through the patient’s treatment. Given the research findings, it would be difficult to see why patients who are adequately supported in the decision-making process would be choosing surgery over physiotherapy.”

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Author | Interim Planned Care Lead, NHS North Kirklees & NHS Wakefield CCG
Clinical Reviewers | GP NHS North Kirklees
| National Clinical Manager and Regional Clinical Lead, Connect Health
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Responsible Officers | Interim Chief Operating Officer, North Kirklees & Wakefield CCG
| NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care
References:
1. Painful osteoarthritis of the knee - Royal college of surgeons/BOA commissioning guide November 2013
3. Care and Management of Osteoarthritis NICE Clinical Guidelines CG177 Feb 2014 http://www.nice.org.uk/guidance/GC177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-
http://www.bmj.com/content/350/bmj.h2747
17. Arthroscopic surgery for knee pain. A highly questionable practice without supporting evidence of even moderate quality BMJ2016; 354 doi: http://dx.doi.org/10.1136/bmj.i3934 (Published 20 July 2016)
23. Bryan S et al. The cost-effectiveness of magnetic resonance imaging for
32. Arthroscopic surgery for knee pain; where is the shared decision making? Letter from Dr S Finnikin GP http://www.bmj.com/content/354/bmj.j3934/rr/927387
33. Osteoarthritis of the knee shared decision-making tool
34. Orthopaedic groups apologise after claiming that ‘GPs not doing their job properly’ http://www.pulsetoday.co.uk/clinical/more-clinical-areas/musculoskeletal/orthopaedic-groups-apologise-after-claiming-that-gps-not-doing-their-job-properly/20010420. full article
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<tr>
<td>PROCEDURE/TREATMENT</td>
<td>10.1.4 - KNEE REPLACEMENT FOR KNEE ARTHRITIS OSCAR REF: PA4 05/2017</td>
</tr>
</tbody>
</table>
| ELIGIBILITY CRITERIA | Referral should be when other pre-existing medical conditions have been optimised AND Conservative measures have been exhausted and failed. This will include weight reduction, NSAIDs and analgesics, changing activity, and introducing a walking aid.  

*Please refer to the classification of pain levels and functional limitations in the table below.*

Referrals should be made if any one of the three following applies:

- The patient complains of intense or severe symptomatology and
  - Has radiological features of severe disease
  - Has demonstrated disease within all three compartments of the knee (tri-compartmental) or localised to one compartment plus patello-femoral disease (bi-compartmental)
- The patient complains of intense or severe symptomatology and
  - Has radiologic features of moderate disease
  - Is troubled by limited mobility or stability of the knee joint.
- The patient has severe symptomatology
  - Has radiological features of slight disease
  - Is troubled by limited mobility or stability of the knee joint.

The patient is fit for surgery with a BMI ≤30. Patients with a BMI >30 should be advised and given appropriate support to address lifestyle factors that would improve their fitness for surgery.

There is evidence to show that “Weight loss and exercise combined have been shown to achieve the same level of symptom relief as joint replacement surgery”

- A study of obese patients with osteoarthritis found that those who dropped their weight by 10% after a combination of diet and exercise reported less pain, better knee function, improved mobility and enhanced quality of life. NICE Guidance:
  - [https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-2](https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-2)

BMI is an established measure of weight though it is recognised that muscular
people will have a higher BMI that is not thought to be a risk to health (muscle is denser than fat)

**Waist circumference**

Obesity can be measured by waist measurements but it is not yet established in UK clinical practice. NHS Choices website states individuals have a higher risk of health problems if waist size is:

- more than 94cm (37 inches) if you're a man
- more than 80cm (31.5 inches) if you're a woman

Risk of health problems is even higher if your waist size is:

- more than 102cm (40 inches) if you're a man
- more than 88cm (34.5 inches) if you're a woman

Referrals will not be accepted if the patient has an Oxford Knee Score greater than or equal to 20. This scoring should be completed in Primary Care prior to referral.

- The tool can be found at: [http://www.orthopaedicscore.com/scorepages/oxford_knee_score.html](http://www.orthopaedicscore.com/scorepages/oxford_knee_score.html)
- Further guidance available at: [http://www.bjj.boneandjoint.org.uk/content/89-B/8/1010.full](http://www.bjj.boneandjoint.org.uk/content/89-B/8/1010.full)

Evidence suggests that the following patients would be INAPPROPRIATE candidates for knee joint replacement surgery:

- Where the patient complains of mild joint pain AND has minor or moderate functional limitation
- Where the patient complains of moderate to severe joint pain AND has minor functional limitation AND has not previously had an adequate trial of conservative management as described above

Patients whom are assessed by the above criteria to be inappropriate for knee replacement surgery should not be listed for surgery.

**For Knee Replacement: Classification of Mobility, Stability, Symptomatology, Radiology and Localisation**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility and Stability</td>
<td></td>
</tr>
<tr>
<td>Preserved mobility and stable joint</td>
<td>Preserved mobility is equivalent to minimum range of movement from 0o to 90o. Stable or not lax is equivalent to an absence of slackness of more than 5mm in the extended joint.</td>
</tr>
<tr>
<td>Limited mobility and/or stable joint</td>
<td>Limited mobility is equivalent to a range of movement less than 0o to 90o unstable or lax is equivalent to the presence of slackness of more than 5mm in the extended joint.</td>
</tr>
<tr>
<td>Symptomatology</td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>Sporadic pain. Pain when climbing/descending stairs.</td>
</tr>
</tbody>
</table>
**Moderate**

- Occasional pain.
- Pain when walking on level surfaces (half an hour, or standing).
- Some limitation of daily activities.
- Medication, aspirin, paracetamol or NSAIDs to control with no/few side effects.

**Intense**

- Pain of almost continuous nature.
- Pain when walking short distances on level surfaces or standing for less than half an hour.
- Daily activities significantly limited.
- Continuous use of NSAIDs for treatment to take effect.
- Requires the sporadic use of support systems walking stick, crutches.

**Severe**

- Continuous pain.
- Pain when resting.
- Daily activities significantly limited constantly.
- Continuous use of analgesics - narcotics/NSAIDs with adverse effects or no response.
- Requires more constant use of support systems (walking stick, crutches).

**Radiology**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>Ahlback grade I.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Ahlback grade II and III.</td>
</tr>
<tr>
<td>Severe</td>
<td>Ahlback grade IV and V</td>
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**Localisation**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unicompartmental</td>
<td>Excluded patello-femoral isolated.</td>
</tr>
<tr>
<td>Bicompartmental</td>
<td>Unicompartmental plus patello-femoral.</td>
</tr>
<tr>
<td>Tricompartmental</td>
<td>Disease affecting all three compartments of the knee.</td>
</tr>
</tbody>
</table>

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical
complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

<table>
<thead>
<tr>
<th>Summary of evidence / rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Around 450 patients per 100,000 population will present to primary care with hip pain each year. Of these, 25% will improve within three months and 35% at twelve months; this improvement is sustained.</td>
</tr>
</tbody>
</table>

20% of adults over 50 and 40% over 80 years’ report disability from knee pain secondary to osteoarthritis. The majority of patients present to primary care with symptoms of pain and stiffness, which reduces mobility and with associated reduction in quality of life.

Osteoarthritis may not be progressive and most patients will not need surgery, with their symptoms adequately controlled by non-surgical measures, as outlined by NICE. Symptoms progress in 15% of patients with hip pain within 3 years and 28% within 6 years.

When patient’s symptoms are not controlled by up to 3 months of non-operative treatment they become candidates for assessment for joint surgery. The decision to have joint surgery is based on the patient’s pre-operative levels of symptoms, their capacity to benefit, their expectation of the outcome and attitude to the risks involved. Patients should make shared decisions with clinicians, using decision support such as the NHS Decision Aid for knee osteoarthritis.

Obesity is an increasing problem in the population and also a significant risk factor for osteoarthritis. It is often associated with comorbidities such as diabetes, IHD, HT and sleep apnoea. Some years ago, an Arthritis Research Campaign Report stated that joint surgery is less successful in obese patients because obese patients have a significantly higher risk of a range of short-term complications during and immediately after surgery (e.g. longer operations, excess blood loss requiring transfusions, DVT, wound complications including infection).

The heavier the patient, the less likely it is that surgery will bring about an improvement in symptoms (e.g. they are less likely to regain normal functioning or reduction in pain and stiffness)

The implant is likely to fail more quickly, requiring further surgery (e.g. within 7 years, obese patients are more than 10 times as likely to have an implant failure); People who have joint replacement surgery because of obesity-related
osteoarthritis are more likely to gain weight post-operatively (despite the new opportunity to lose weight through exercise following reduction in pain levels). It also concluded that “Weight loss and exercise combined have been shown to achieve the same level of symptom relief as joint replacement surgery”. A study of obese patients with knee osteoarthritis found that those who dropped their weight by 10% after a combination of diet and exercise reported less pain, better knee function, improved mobility and enhanced quality of life.11

A recent extensive literature review advises assessment of “timely weight loss as a part of conservative care”12. It confirms in detail the increased risk of many perioperative and postoperative complications associated with obesity (as well as increased costs and length of stay), such as wound healing/infections; respiratory problems; thromboembolic disease; dislocation; need for revision surgery; component malposition; and prosthesis loosening.

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<tr>
<th>Date effective from</th>
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<tbody>
<tr>
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<tr>
<td>Author</td>
<td>Interim Planned Care Lead, NHS North Kirklees &amp; NHS Wakefield CCG</td>
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<tr>
<td>Responsible Officers</td>
<td>Interim Chief Operating Officer, North Kirklees &amp; Wakefield CCG NHS North Kirklees CCG &amp; NHS Wakefield CCGs GP Leads Planned Care</td>
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</tbody>
</table>
4. Optimising Outcomes from Elective Surgery Commissioning Statement Statement number: 01(link when PDF done)  
5. Obesity prevention NICE CG 43 Dec 2006; last amended March 2015 https://www.nice.org.uk/guidance/cg43  
6. RightCare shared decision-making tools  
7. NHS Choices: http://www.nhs.uk/chq/Pages/849.aspx?CategoryId=51&SubCategoryId=165 |
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<td>STATUS</td>
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<tr>
<td>PROCEDURE /TREATMENT</td>
<td>10.1.5 - ARTHROSCOPIC FEMORO-ACETABULAR SURGERY FOR HIP IMPINGEMENT SURGERY (HIP ARTHROSCOPY)</td>
</tr>
<tr>
<td>EXCLUSIONS</td>
<td>Red flag symptoms or signs include recent trauma, constant progressive non-mechanical pain (particularly at night) previous history of cancer, long term oral steroid use history of drug abuse or HIV, fever, being systematically unwell, recent unexplained weight loss, persistent severe restriction of joint movement, widespread neurological changes, and structural deformity. Red flag conditions include infection, carcinoma, nerve root impingement, bony fracture and avascular necrosis</td>
</tr>
<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Current evidence on safety and efficacy does not appear adequate to recommend hip arthroscopy other than as listed below. On this basis, the CCGs would not routinely support Hip Arthroscopy.</td>
</tr>
</tbody>
</table>

The commissioning of hip arthroscopy (from surgeons with specialist expertise in this type of surgery) is in line with the requirements stipulated by NICE IPG 408 and only for patients who fulfil ALL of the following criteria:

- A definite diagnosis of hip impingement syndrome /femoro-acetabular impingement (FAI) has been made by appropriate investigations, X-rays, MRI and CT scans
- An orthopaedic surgeon who specialises in young adult hip surgery has made the diagnosis in collaboration with a specialist musculoskeletal radiologist
- The patient has had severe FAI symptoms (restriction of movement, pain and ‘clicking’) or significantly compromised functioning for at least 6 months
- The symptoms have not responded to all available conservative treatment options including activity modification, drug therapy (NSAIDs) and specialist physiotherapy

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery
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- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

### Summary of evidence / rationale

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Hip impingement syndrome is caused by abnormal contact between the top of the thigh bone and the hip socket. This results in ‘clicking’ of the hip, limited movement and pain, which can be made worse when the hip is bent or after sitting for a long time. The condition may be caused by an unusually shaped thigh bone or hip socket and usually affects young, often active people. Hip impingement syndrome is usually managed by changes to lifestyle and drug treatment. Treatment via hip arthroscopy has evolved greatly in the last decade with improvements in the available technology, and in Sept 2011 NICE issued IPG 408 on arthroscopic femoroacetabular surgery for hip impingement syndrome. The aim of the procedure is to reduce pain and improve the hip-joint range of movement. With the patient under general anaesthetic, a thin telescope (arthroscope) is inserted into the hip joint through a small cut in the skin. The surgeon then makes further cuts and uses instruments to remove some of the cartilage and/or bone in order to reshape the joint surfaces.

The guidance states that current evidence on the efficacy of this treatment is adequate in terms of symptom relief in the short and medium term and may possibly delay progression to osteoarthritis. In terms of safety it states that complications (which occur in up to 5% of cases) are ‘well recognised’, usually adverse events relating to the significant traction required during the technically demanding procedure. The guidance stipulates that details of all patients undergoing this procedure should be entered into a register established by the British Hip Society.

NICE concludes that despite some methodological drawbacks in the studies, no RCT evidence, and the paucity of evidence on treatment outcomes beyond two years, the available efficacy evidence appears adequate, key outcomes for this procedure include improved function and quality of life, pain relief and delayed progression to osteoarthritis in some patients.
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<td>PROCEDURE/ TREATMENT</td>
<td>10.1.6 - HIP REPLACEMENT FOR HIP ARTHRITIS</td>
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<td></td>
<td>OSCAR REF: PA6 05/2017</td>
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</table>
| EXCLUSIONS       | Referral should be when other pre-existing medical conditions have been optimised AND Conservative measures have been exhausted and failed. This will include weight reduction, NSAIDs and analgesics, changing activity, and introducing a walking aid. Please refer to the classification of pain levels and functional limitations in the table below. Referrals should be made if any one of the three following applies: 1. The patient complains of severe joint pain and   - Has radiological features of moderate to severe disease   - Has severe functional limitation irrespective of whether conservative management has been trialled 2. The patient complains of severe joint pain   - Has radiological features of moderate to severe disease   - Has minor to moderate functional limitation, despite the use of non-surgical treatments such as adequate doses of NSAID analgesia, weight control treatments and physical therapies. 3. The patient complains of mild to moderate joint pain   - Has radiological features of moderate to severe disease   - Has severe functional limitation, despite the use of non-surgical treatments such as adequate doses of NSAID analgesia, weight control treatments and physical therapies   - Is assessed to be at low surgical risk. The patient is fit for surgery with a BMI ≤30. Patients with a BMI >30 should be advised and given appropriate support to address lifestyle factors that would improve their fitness for surgery. There is evidence to show that “Weight loss and exercise combined have been shown to achieve the same level of symptom relief as joint replacement surgery”. A study of obese patients with osteoarthritis found that those who dropped their weight by 10% after a combination of diet and exercise reported less pain, better knee function, improved mobility and enhanced quality of life. NICE Guidance:  - [https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-2](https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-2)  - [https://www.nice.org.uk/guidance/cg189/chapter/1-](https://www.nice.org.uk/guidance/cg189/chapter/1-)
Recommendations\#identification-and-classification-of-overweight-and-obesity

BMI is an established measure of weight though it is recognised that muscular people will have a higher BMI that is not thought to be a risk to health (muscle is denser than fat)

Waist circumference
Obesity can be measured by waist measurements but it is not yet established in UK clinical practice. NHS Choices website states individuals have a higher risk of health problems if waist size is:
- more than 94cm (37 inches) if you're a man
- more than 80cm (31.5 inches) if you're a woman
Risk of health problems is even higher if your waist size is:
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Referrals will not be accepted if the patient has an Oxford Hip Score greater than or equal to 20. This scoring should be completed in Primary Care prior to referral.
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Evidence suggests that the following patients would be INAPPROPRIATE candidates for hip joint replacement surgery:
- Where the patient complains of mild joint pain AND has minor or moderate functional limitation
- Where the patient complains of moderate to severe joint pain AND has minor functional limitation AND has not previously had an adequate trial of conservative management as described above

Patients whom are assessed by the above criteria to be inappropriate for hip replacement surgery should not be listed for surgery.

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<th>Hip replacement: Classification of Pain Levels and Functional Limitations</th>
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<tbody>
<tr>
<td><strong>Variable</strong></td>
</tr>
<tr>
<td><strong>Pain Level</strong></td>
</tr>
<tr>
<td>Mild</td>
</tr>
<tr>
<td>Moderate</td>
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</tbody>
</table>
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. |

**Previous non-surgical treatments**

| Correctly Done | NSAIDs, paracetamol, aspirin or narcotic analgesics at regular doses during 6 months with no pain relief; weight control treatment if overweight, physical therapies done. |
| Incorrectly Done | NSAIDs, paracetamol, aspirin or narcotic analgesics at inadequate doses or less than 6 months with no pain relief; or no weight control treatment if overweight or no physical therapies done. |

**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. |

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications
with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encouraging more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

<table>
<thead>
<tr>
<th>Summary of evidence / rationale</th>
<th>Around 450 patients per 100,000 population will present to primary care with hip pain each year. Of these, 25% will improve within three months and 35% at twelve months; this improvement is sustained.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>20% of adults over 50 and 40% over 80 years’ report disability from knee pain secondary to osteoarthritis. The majority of patients present to primary care with symptoms of pain and stiffness, which reduces mobility and with associated reduction in quality of life. Osteoarthritis may not be progressive and most patients will not need surgery, with their symptoms adequately controlled by non-surgical measures, as outlined by NICE. Symptoms progress in 15% of patients with hip pain within 3 years and 28% within 6 years.</td>
</tr>
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<td>When patient’s symptoms are not controlled by up to 3 months of non-operative treatment they become candidates for assessment for joint surgery. The decision to have joint surgery is based on the patient’s pre-operative levels of symptoms, their capacity to benefit, their expectation of the outcome and attitude to the risks involved. Patients should make shared decisions with clinicians, using decision support such as the NHS Decision Aid for hip osteoarthritis.</td>
</tr>
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<td>Obesity is an increasing problem in the population and also a significant risk factor for osteoarthritis. It is often associated with comorbidities such as diabetes, IHD, HT and sleep apnoea. Some years ago, an Arthritis Research Campaign Report stated that joint surgery is less successful in obese patients because</td>
</tr>
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<td>Obese patients have a significantly higher risk of a range of short-term complications during and immediately after surgery (e.g. longer operations, excess blood loss requiring transfusions, DVT, wound complications including infection).</td>
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<td>The heavier the patient, the less likely it is that surgery will bring about an improvement in symptoms (e.g. they are less likely to regain normal functioning or reduction in pain and stiffness) The implant is likely to fail more quickly, requiring further surgery (e.g. within 7 years, obese patients are more than 10 times as likely to have an implant failure);</td>
</tr>
</tbody>
</table>
People who have joint replacement surgery because of obesity-related osteoarthritis are more likely to gain weight post-operatively (despite the new opportunity to lose weight through exercise following reduction in pain levels).

It also concluded that “Weight loss and exercise combined have been shown to achieve the same level of symptom relief as joint replacement surgery”. A study of obese patients with knee osteoarthritis found that those who dropped their weight by 10% after a combination of diet and exercise reported less pain, better Hip function, improved mobility and enhanced quality of life.11.

A recent extensive literature review advises assessment of “timely weight loss as a part of conservative care”12. It confirms in detail the increased risk of many perioperative and postoperative complications associated with obesity (as well as increased costs and length of stay), such as wound healing/infections; respiratory problems; thromboembolic disease; dislocation; need for revision surgery; component malposition; and prosthesis loosening.

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| Responsible Officer| Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
|                    | NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
| References         | 1. RightCare Commissioning for Value Focus Pack for Vale of York CCG  
|                    | https://www.england.nhs.uk/resources/resources-for-ccgs/comm-for-value/north-region/#53  
|                    | 2. NHS Vale of York Clinical Commissioning Group - Prevention and Better Health Strategy  
|                    | 3. Care and Management of Osteoarthritis NICE Clinical Guidelines CG177 Feb 2014  
|                    | http://www.nice.org.uk/guidance/CG177/chapter/1-Recommendations#referral-for-consideration-of-joint-surgery-  
|                    | 4. Optimising Outcomes from Elective Surgery Commissioning Statement  
|                    | Statement number: 01(link when PDF done)  
|                    | 5. Obesity prevention NICE CG 43 Dec 2006; last amended March 2015  
|                    | https://www.nice.org.uk/guidance/cg43  
|                    | 6. RightCare shared decision-making tools |
7. NHS Choices:  
http://www.nhs.uk/chq/Pages/849.aspx?CategoryID=51&SubCategoryID=165
8. Royal College of Surgeons Commissioning Guides: Painful osteoarthritis of the hip November 2013  
http://www.rcseng.ac.uk/healthcare-bodies/docs/commissioning-guides-boa/painful-hip-commissioning-guide
9. Royal College of Surgeons Commissioning Guides: Painful osteoarthritis of the knee November 2013  
http://www.arthroplastyjournal.org/article/S0883-5403(13)00174-5/abstract
**Policy Statement**

**Commissioning Policy**

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<th>Status</th>
<th>Criteria Led or Prior Approval Required</th>
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**Procedure / Treatment**

10.1.7 - Excision Acromioclavicular Joint (Shoulder Arthroscopy)

OSCAR PA7 05/2017

**Exclusions**

Where is not appropriate to use Manipulation under anaesthetic:

- Frozen shoulder associated with insulin-dependent diabetes does not respond well to manipulation under anesthesia, often refreezing within 2 to 3 weeks. If there is any history of postirradiation fibrosis, then this may well lead to loss of elasticity in the brachial plexus and put the plexus in jeopardy of a traction lesion.
- The elderly, frail, and osteoporotic should not be manipulated for fear of causing a fracture of the shaft or proximal humerus.

**Eligibility Criteria**

Shoulder arthroscopy will only be funded for patients with adhesive capsulitis (‘frozen shoulder’) if the following treatments have all been tried and failed:

a) Activity modification
b) Physiotherapy and exercise programme
c) Oral analgesics including NSAIDs (unless contraindicated)
d) Intra-articular steroid injections
e) Manipulation under anaesthetic

GPs should not refer unless all the above have been tried and failed, and referrals must include objective information to demonstrate this.

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suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>1. Shoulderdoc.com - Manipulation under Anaesthesia - <a href="https://www.shoulderdoc.co.uk/article/1223">https://www.shoulderdoc.co.uk/article/1223</a>.</td>
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managed or supervised weight reduction programme, have lost at least 5% weight.

- Symptoms are refractory to behavioural interventions: a minimum of 6 weeks of bladder retraining OR 3 months of pelvic floor muscle training (in mixed UI only, where there is some stress incontinence as well as OAB)
- Symptoms are refractory to 4 weeks of anticholinergic medication to a maximal tolerated dose (a number of drugs may be tried in accordance with NICE CG171) [OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective or have unacceptable side effects (NICE TA290)]
- The woman has been referred to secondary care, reviewed by an MDT and a diagnosis of detrusor over activity has been confirmed by urodynamic assessment
- Symptoms are refractory to injections of Botulinum Toxin Type A into the bladder wall (only in patients willing and able to perform clean intermittent catheterisation). (NB If Botox has not been tried, the IFR should include a valid clinical explanation for this)
- Symptoms are refractory to behavioural and lifestyle modification (diet, weight management, modification of fluid intake):
  - Bladder retraining
  - Bladder catheterisation
  - The woman has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT

**Men**

Requests for SNS from a Consultant Urologist for men with overactive bladder (OAB) caused by detrusor over activity who fulfil ALL the following criteria:

- Symptoms are refractory to conservative management lifestyle advice, advice on fluid intake, supervised bladder training and use of containment products (pads, sheaths, etc.)
- Symptoms are refractory to 4-6 weeks of anticholinergic medication [OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290)]
- The man has been referred to secondary care for specialist assessment and a diagnosis of detrusor over activity has been confirmed
- Symptoms are refractory to injections of Botulinum Toxin Type A into the bladder wall (only in patients willing and able to self-catheterise). (NB If Botox has not been tried, the IFR should include a valid clinical explanation for this)

Before a temporary SNS device is fitted, ALL prospective patients must be:

- Able to record voiding diary data so that clinical results of the implantation can be evaluated
- Fully informed of the risks and benefits of the procedure and, therefore, able to
make an appropriate choice and consent to treatment

Before a permanent SNS device is fitted, ALL prospective patients must have been approved for and have undergone a positive trial period (2-3 weeks) of temporary stimulation resulting in a 50% or greater improvement in voiding function based on the results of a voiding diary.

SNS will not be commissioned for patients with:

- Stress incontinence, the most common type of urinary dysfunction
- Urinary retention due to obstruction (e.g. from benign prostatic hypertrophy, cancer, or urethral stricture)
- Urge incontinence due to psychological or neurological conditions, such as diabetes with peripheral nerve involvement, MS, stroke or spinal cord injury (see NICE CG 148)

**Spinal cord stimulation is recommended as a possible treatment for adults with chronic pain of neuropathic origin if they:**

- continue to experience chronic pain (measuring at least 50 mm on a 0-100 mm visual analogue scale) for at least 6 months despite standard treatments, and
- have had a successful trial of spinal cord stimulation as part of an assessment by a specialist team.
- Treatment with spinal cord stimulation should only be given after the person has been assessed by a specialist team experienced in assessing and managing people receiving treatment with spinal cord stimulation.

The CCG will not routinely fund high frequency stimulators.

Re-chargeable batteries for implantable pulse generators will be funded where this avoids the need for further surgery. It is expected that where there are different systems of equal effectiveness, the least costly system is used.

The CCG does not commission Spinal Cord Stimulation as a treatment option for adults with chronic pain of ischaemic origin.

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| PROCEDURE/TREATMENT | 10.1.9 - HALLUX VALGUS – SURGERY   
OSCAR REF: PA9 05/2017 |
|                  | A bunion is a deformity of the joint connecting the big toe to the foot and is known as Hallux Valgus. It is characterized by medial deviation of the first metatarsal bone and lateral deviation of the Hallux (Big Toe) |
| EXCLUSIONS       | Where URGENT referral via existing diabetic foot pathway is required |
| ELIGIBILITY CRITERIA | • Have been seen, assessed and treated within podiatry services   
• All appropriate conservative measures have been tried over a 6-month period and failed to relieve symptoms, including: up to 12 weeks of evidence based non-surgical treatments, i.e. Analgesics/ painkillers. bunion pads, footwear modifications   
• The patient suffers from severe pain on walking (not relieved by chronic standard analgesia) that causes significant functional impairment interfering with Actively of Daily Living (ADLs) i.e. ability to: work, attend education, ability to manage simple domestic duties, ability to manage as a carer   
OR   
• Severe deformity (with or without lesser toe deformity) that causes significant functional impairment OR prevents them from finding adequate footwear   
• Recurrent or chronic ulceration or infection   
• Understands post-operative pathway including:   
  ✓ 6-week post-operative period with plaster cast and may involve absence from work for sedentary work of 2-6 weeks and a possible 2-3 months for physical work   
  ✓ 6-8 weeks’ post-operative period without driving (2 weeks if left side and driving automatic car)   
  ✓ Full function will be limited for approximately 4 months   
  ✓ Treatment prognosis is highly variable   
  ✓ There is a higher risk of ulceration or other complications, for example, neuropathy, for patients with diabetes. Such patients should be referred for an early assessment. A patient should not be referred for surgery for prophylactic or cosmetic reasons for asymptomatic bunions. |
Note: Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Funding Request Form see Appendix 2)

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Summary of evidence / rationale

NICE Clinical Knowledge Summaries (CKS) makes clear that referral for bunion surgery is indicated for pain and is not routinely performed for cosmetic purposes1. Conservative treatment may be more appropriate than surgery for some older people, or people with severe neuropathy or other comorbidities affecting their ability to undergo surgery. Referral for orthopaedic or podiatric surgery consultation may be of benefit if the deformity is painful and worsening; the second toe is involved; the person has difficulty obtaining suitable shoes; or there is significant disruption to lifestyle or activities.

If the person is referred for consideration of surgery, advise that surgery is usually done as a day case. Bunion surgery may help relieve pain and improve the alignment of the toe in most people (85%–90%); but there is no guarantee that the foot will be perfectly straight or pain-free after surgery. Complications after bunion surgery may include infection, joint stiffness, transfer pain (pain under the ball of the foot), hallux varus (overcorrection), bunion recurrence, damage to the nerves, and continued long-term pain.

There is very little good evidence with which to assess the effectiveness of either conservative or operative treatments or the potential benefit of one over the other.

Untreated HV in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even amputation.
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| Reference           | 1. NICE Clinical Knowledge Summaries [http://cks.nice.org.uk/bunions](http://cks.nice.org.uk/bunions)  
|                     | 2. Royal College of Surgeons Painful deformed great toe (2013) – under revision  
|                     | 5. NICE. Surgical correction of hallux valgus using minimal access techniques. 332. London: National Institute for Health and Clinical Excellence; 2010  
Dupuytren's contracture (Dupuytren's disease) is a condition that affects the hands and fingers. It causes one or more fingers to bend into the palm of the hand. It can affect one or both hands, and sometimes affect the thumb.

**EXCLUSIONS**

Management of Dupuytren’s Contracture depends on the stage of the disease. Dupuytren’s can still be classified as mild, moderate and severe to guide treatment options:

**Table 1: Staging of Dupuytren’s disease**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Deformity</th>
<th>Equivalence to grading used in original GM policy for multiple joint disease</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>No lesion</td>
<td>No disease</td>
</tr>
<tr>
<td>N</td>
<td>Palmar nodule without presence of contracture</td>
<td>Minimal early disease</td>
</tr>
<tr>
<td>1</td>
<td>TFD between 0° and 45</td>
<td>Mild disease in a single join</td>
</tr>
<tr>
<td>2</td>
<td>TFD between 45° and 90°</td>
<td>Moderate</td>
</tr>
<tr>
<td>3</td>
<td>TFD between 90° and 135°</td>
<td>Severe</td>
</tr>
<tr>
<td>4</td>
<td>TFD greater than 135°</td>
<td>Severe</td>
</tr>
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</table>

Surgery of Dupuytren’s contracture will only be funded in accordance with the criteria specified below:

- Flexion deformity >30° at the MCPJoint or PIPJoint OR
- Rapidly progressive disease OR
- Contracture interferes with lifestyle and/or occupation

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### Summary of evidence / rationale

**Dupuytren’s Contracture** is a challenging condition for which there is no satisfactory treatment. All the treatments have high re-occurrence rates and carry the risk of complications.

The evidence from the Systematic Reviews suggests that Fasciectomy has far lower recurrence rates than fasciotomy.

Dupuytren's disease is a benign, slowly progressive condition of unknown origin, characterised by connective tissue thickening in the palm of the hand, forming nodules and cords, which leads to difficulty in extending the fingers. Symptoms are often mild and painless and do not require treatment but can include reduced range of motion, reduced hand function and pain. Most patients are affected in both hands. Most patients do not need treatment, but regular follow-up is needed to detect early joint contracture - this can pull the joints into a permanently flexed position, making it difficult to perform activities of daily living. The condition often occurs in later life, and is most common in men who are aged over 40. Around one in six men over the age of 65 are affected in the UK.

Intervention is almost exclusively surgical but surgery is not curative and recurrence rates can be high. To justify the risks of surgery a flexion deformity must be present.

Although there is great variation in the rate of progress, it is usually possible to distinguish the more aggressive form of the disease early on. Recurrence is more likely in younger patients if the original contracture was severe or if there is a strong family history of the condition.
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<td>10.1.11 - CARPAL TUNNEL SURGERY FOR THE TREATMENT OF CARPAL TUNNEL SYNDROME (CTS) OSCAR REF: PA11 05/2017</td>
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Carpal tunnel surgery, also called carpal tunnel release (CTR) and carpal tunnel decompression surgery, is a surgery in which the transverse carpal ligament is divided. It is a treatment for carpal tunnel syndrome.

This commissioning policy is needed in order to clarify the criteria for referral to secondary care for the treatment of carpal tunnel syndrome.

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<tr>
<th>ELIGIBILITY CRITERIA</th>
<th>Where a diagnosis of CTS is certain (where there is diagnostic uncertainty a specialist opinion is required) and one of the following criteria:</th>
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<td>1) Moderate symptoms - The patient has not responded to a minimum of 3 months of conservative management, including:</td>
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<td>• &gt;12 weeks of night-time use of wrist splints AND/OR Corticosteroid injections in appropriate patients</td>
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<td>• The symptoms are interfering with activities of daily living</td>
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<td>2) Advanced or severe neurological symptoms of CTS such as constant pins and needles, numbness, muscle wasting and prominent pain</td>
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<td></td>
<td>3) The patient is suffering from significant functional impairment*, pain or sleep deprivation</td>
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<td>*Significant functional impairment is defined as a loss or absence of an individual's capacity to meet personal, social or occupational demands</td>
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**NOTE:** Nerve conduction studies are NOT generally needed to confirm the diagnosis. In elderly patients, with insidious onset nerve conduction studies may be useful to assess severity.

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)
### NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with 'Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

### Summary of evidence / rationale

CTS is a condition that involves pain and tingling in the first three or four fingers of one or both hands, which usually occurs at night. It is caused by pressure on the median nerve as it passes under the strong ligament that lies across the front of the wrist. Mild or moderate symptoms often resolve within 6 months. This is most likely to occur in young people (less than 30 years of age), if the symptoms are unilateral and of short duration, and in women in whom fluid retention due to pregnancy is the precipitating factor. With wearing a wrist splint that maintains the wrist at a neutral angle without applying direct compression, any improvement should be apparent within 12 weeks of use.

Acupuncture may be effective for pain relief in the short-term, although there is no therapeutic benefit. Minimization of activities that exacerbate symptoms may help, but for people who work with computer keyboards there is little evidence to suggest that modifications at their work place are likely to be of any help in relieving symptoms.

CTS can also be a progressive condition, but many patients have a satisfactory response to conservative management. If CTS does not respond to conservative treatment within 6 months, evidence suggests that it is unlikely to respond at all.

GPs are advised to pursue conservative options for treatment of mild to moderate CTS cases. Only where the case is severe, or where a moderate case persists and fails to respond to a minimum of 6-months’ conservative treatment should a referral to secondary care be considered.

A systematic review concluded that:

- Corticosteroids (local injection) and surgery versus no treatment are 'likely to
be beneficial’

- Surgery versus wrist splints or local corticosteroid injection are both ‘a trade-off between benefits and harms’.
- Therapeutic ultrasound and wrist splints are both of ‘unknown effectiveness’.

Surgical carpal tunnel decompression can provide permanent and complete cure in most cases of severe CTS but it is not without risk. A survey of over 4000 patients having surgery under usual NHS circumstances found that about two years after surgery, only 75% considered the operation an unqualified success and 8% thought that they were worse off. Reasons why the operation sometimes may not relieve symptoms include:

- **Misdiagnosis**
- Failure to fully divide the transverse carpal ligament
- Delay of treatment to a point when median nerve function is beyond recovery
- (A small minority are the result of more unpredictable surgical complications, inadvertent nerve and vessel lacerations, infections, painful scarring, and complex regional pain syndrome.)

Overall, patients whose CTS symptoms are significantly troublesome and who have mild or moderate impairment of the median nerve function should be offered splinting and local steroid injection. Patients failing such conservative management and those who present at a later stage with objective neurological signs or delayed motor conduction on nerve conduction systems should be offered the option of surgical decompression. All should be advised of the potential risks of the different treatments.

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| References:         | 1) NICE CKS Carpal tunnel syndrome [http://cks.nice.org.uk/carpal-tunnel-syndrome#!scenariorecommendation:2](http://cks.nice.org.uk/carpal-tunnel-syndrome#!scenariorecommendation:2)  
2) Clinical Evidence – Carpal Tunnel Syndrome updated August 2014 [http://clinicalevidence.bmj.com/ceweb/conditions/msd/1114/1114.jsp](http://clinicalevidence.bmj.com/ceweb/conditions/msd/1114/1114.jsp)  
|   | 2007;335:p343- 346  
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1949464/  
5) BSSH Evidence for Surgical Treatment 1 - CTS 2010  
http://www.bssh.ac.uk/education/guidelines/carpal_tunnel_syndrome.pdf  
6) Royal College of Surgeons Commissioning Guide: Treatment of painful tingling fingers (November 2013) - currently under review  
7) https://southwest.devonformularyguidance.nhs.uk/referralguidance/western-locality/musculoskeletal/carpal-tunnel  
9) Patient Info - Carpal Tunnel Syndrome https://patient.info/decision-aids/carpal-tunnel-syndrome-decision |
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<td>PROCEDURE/TREATMENT</td>
<td>10.1.12 - TONSILLETOXY FOR RECURRENT TONSILLITIS - ADULTS AND CHILDREN</td>
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Tonsillectomy is one of the most common surgical procedures in the UK. There is good evidence for the effectiveness of tonsillectomy in selected children, but only limited evidence in adults.

This commissioning policy is needed in order to clarify the ELIGIBILITY CRITERIA for referral to secondary care for surgery for recurrent tonsillitis.

EXCLUSIONS
- Urgent referral is required for
  - Peritonsillar abscess (quinsy)
  - Adult obstructive sleep apnoea with tonsillar enlargement (if trials of continuous positive airway pressure (CPAP) and the use of mandibular advancement devices are unavailable or unsuccessful).
  - Severe neck infection
  - Excluding possible malignancy e.g. lymphoma
  - Sleep disordered breathing (apnoea) in children
  - Patients with sore throat who have stridor, progressive dysphagia, bleeding, increasing pain or severe systemic symptoms (may require hospital admission)
  - Tonsil bleeding

ELIGIBILITY CRITERIA
- Recurrent acute sore throat due to tonsillitis AND
  - The frequency of episodes of acute tonsillitis is confirmed by the patient's GP or appropriately trained member of clinical team as follows:
    - 7 or more well documented, clinically significant, adequately treated episodes of tonsillitis in the last year;
    - 5 or more such episodes per year in the preceding two years;
    - 3 or more such episodes per year in the preceding three years;
  - There has been significant impact on quality of life indicated by documented evidence of symptoms that act as a barrier to employment or education or carrying out carer activities; OR Failure to thrive
  - Marked tonsillar asymmetry, which there is clinical suspicion sinister pathology
  - Halitosis thought to be caused by tonsils but ONLY where there is clear evidence of tonsillar debris

When in doubt as to whether tonsillectomy would be beneficial, a six-month period of watchful waiting to establish pattern of symptoms and allow time for patient, parents and carers to consider implications of surgery.
Tonsillectomy/adenotonsillectomy will be funded in children under 16 where obstruction of the airway results in obstructive sleep apnoea syndrome, and the following apply:

- A significant impact on development, behaviour and/or quality of life demonstrated by supporting evidence such as growth charts, letters from GPs; OR
- A strong clinical history (± sleep studies) suggestive of sleep apnoea

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**Note: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

| Summary of evidence / rationale | The literature on surgery for recurrent tonsillitis is limited. Most published studies refer to a paediatric population. The quality of the evidence for tonsillectomy in children is poor, but it suggests that surgery may be beneficial in selected cases. The small amount of information about adult sore throat and the effect of tonsillectomy is not scientifically robust but suggests that surgery can be beneficial for recurrent sore throats.

The benefits of surgery compared to non-surgical treatment was the subject of a Cochrane Collaboration review (since updated) which provided additional evidence for the SIGN guidance4, 5. The consensus is that these criteria help to identify patients most likely to gain benefit from surgical intervention but the evidence level is low at 3/4 and clinical judgement is needed to identify patients where exceptionality applies. |
The Cochrane review found no randomised trials in adults and found that the evidence in children was limited by the lack of studies. Two randomised trials were found, but it was not possible to draw conclusions because many of the children also underwent adenoidecтомy [Burton and Glasziou, 2009]. The authors of the Scottish Intercollegiate Guidelines Network (SIGN) guidance commented on:

- Four randomised clinical trials. One trial (which was included in the Cochrane review) found that there was no significant difference between the group that had a tonsillectomy and the group who did not. The other three studies had all taken place before 1972 and no conclusions could be drawn because of methodological flaws.
- Three additional non-controlled studies. These suggested benefits of tonsillectomy for both reducing the number of sore throats, and improving general health.

The evidence on referral criteria for sore throats is based on evidence from a paediatric population. At the time that the referral criteria were written there were no randomised controlled trials concerning the management of recurrent sore throats in adults.

A randomised trial in adults (people over 15 years of age) compared tonsillectomy (n = 36) with watchful waiting (n = 34) [Alho et al, 2007]: Criteria for entry to the trial were three or more episodes of pharyngitis in 6 months, or four or more episodes in 12 months.

The authors concluded that tonsillectomy is an effective alternative for adults with a documented history of recurrent episodes of pharyngitis.

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<td></td>
<td>2. NICE (2005) Referral for suspected cancer (NICE guideline) Clinical</td>
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3. Royal College of Surgeons Commissioning guide Tonsillectomy Sept 2013


   [http://www.sign.ac.uk/guidelines/fulltext/117/index.html](http://www.sign.ac.uk/guidelines/fulltext/117/index.html)


11. DEVON - [https://southwest.devonformularyguidance.nhs.uk/referral-guidance/policies/tonsillectomy](https://southwest.devonformularyguidance.nhs.uk/referral-guidance/policies/tonsillectomy)
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<td>PROCEDURE/TREATMENT</td>
<td>10.1.13 - MYRINGOTOMY/GROMMETS - OTITIS MEDIA WITH EFFUSION (OME) IN CHILDREN UNDER 12</td>
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Glue ear is a common childhood condition where the middle ear becomes filled with fluid (otitis media with effusion or OME). At least 50% of OME causing bilateral hearing loss of at least 20dB will resolve spontaneously within 3 months therefore a period of watchful waiting for at least 3 months is required. Parents should be advised on educational and behavioural strategies to minimise the effects of hearing loss.

Treatment is usually only recommended when symptoms last longer than three months and the hearing loss is thought to be significant enough to interfere with a child’s speech and language development.

For children with recurrent severe middle ear infections, grommets can be inserted into the eardrum under GA to help drain fluid, as a day case procedure, which helps keep the eardrum open for several months. As the eardrum starts to heal, the grommet will slowly be pushed out of the eardrum and will eventually fall out, usually within 6 to 12 months. This process happens naturally and should not be painful.

EXCLUSIONS

Urgent referral for suspicion of cholesteatoma (atypical features and persistent foul discharge) or if OME is complicating sensorineural deafness (eg with excessive hearing loss) or is delaying diagnosis or the patient has treatment with aids or cochlear implants (this would be an indication for immediate grommets)

ELIGIBILITY CRITERIA

- There has been a period of at least three months watchful waiting* from the date of diagnosis of OME (by GP/primary care referrer/audiologist/ENT surgeon) AND OME persists after three months AND the child suffers from persistent bilateral OME with a hearing level in the better ear of 25 dBHL (averaged at 0.5, 1, 2, and 4 kHz) or worse, confirmed over three months OR
- Persistent bilateral OME with a hearing level better than 25 dBHL (averaged at 0.5, 1, 2, and 4 kHz) in the better ear but where the impact of the hearing loss on a child’s developmental, social, or educational status is judged to be significant.

* During the watchful waiting period, advice on educational and behavioural strategies to minimise the effects of hearing loss should be offered. The child’s hearing should be re-tested at the end of this time.

Down’s Syndrome
Hearing aids should normally be offered to children with Down’s syndrome and OME with hearing loss. Before myringotomy/grommets are offered as an alternative to hearing aids for treating OME in children with Down’s syndrome, the following factors should be considered:

- The severity of hearing loss
- the age of the child
- The practicality of ventilation tube insertion
- The risks associated with ventilation tubes
- The likelihood of early extrusion of ventilation tubes

**Cleft Palate**

Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment. Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

**Note:** In children with additional disabilities such as Down’s Syndrome or cleft palate, involvement of a specialist multidisciplinary team with expertise in assessing and treating OME in these children is essential.

**Note:** Do not perform adenoidectomy at the same time unless evidence of persistent and/or frequent upper respiratory tract symptoms/infections

Patients should make shared decisions with clinicians, using Shared Decision-making Aids for Glue Ear

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**Summary of evidence / rationale**

At least 50% of otitis media with effusion (OME) causing bilateral hearing loss of at least 20dB will resolve spontaneously within 3 months therefore a period of watchful waiting for at least 3 months is required\(^1\). Parents should be advised on educational and behavioural strategies to minimise effects of hearing loss. The RCS guidance also states that care should be provided via an integrated care pathway, which should include “prevention through public health programmes to decrease exposure to cigarette smoke during infancy and childhood”\(^1\).

NHS choices points out that factors which increase the risk of getting glue ear include\(^2\):

- growing up in a household where adults smoke
• being bottle fed rather than breastfed as a baby

NICE CKS\(^3\) points out that:
• OME has a very good prognosis. It is a self-limiting illness and 90% of children will have complete resolution within 1 year.
• Active observation for several months (previously known as 'watchful waiting') rarely results in long-term complications.
• There is no proven benefit from treatment with any medications or any complementary or alternative therapies.

NICE clinical guideline 60\(^4\) supports the above criteria and covers:
• The surgical management of OME in children younger than 12 years.
• Guidance for managing OME in children with Down's syndrome and in children with all types of cleft palate.
• It does not specifically look at the management of OME in:
  o Children with other syndromes (for example, craniofacial dysmorphism or polysaccharide storage disease).
  o Children with multiple complex needs.

The NICE pathway is available at here\(^5\).

A Cochrane review\(^6\) concluded in 2010 that "In children with OME the effect of grommets on hearing, as measured by standard tests, appears small and diminishes after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect was found on other child outcomes but data on these were sparse. No study has been performed in children with established speech, language, learning or developmental problems so no conclusions can be made regarding treatment of such children."

NB: Leeds health pathways include the following rarer indications for grommets [http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=2518#appa2](http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=2518#appa2)
• Severe otalgia in otitis media requiring admission, and unresolved with conservative treatment over 3 days
• In immunocompromised patients with otitis media where microbiologic specimens are required
• Complications of otitis media such as meningitis, facial nerve paralysis, coalescent mastoiditis, or brain abscess
• Chronic retraction of the tympanic membrane
• Adults with otitis media with effusion where conservative management has failed over 6 weeks or where malignancy is suspected
• Autophony due to patulous eustachian tube
• As part of treatment for vestibular disorders either alone or with gentamicin

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4. NICE Clinical Guideline 60 Otitis media with effusion in under 12s: surgery (2008) [http://www.nice.org.uk/guidance/CG60](http://www.nice.org.uk/guidance/CG60)
5. NICE Pathway – Surgical management of Otitis Media with effusion in children (2012) [OME with effusion pathway](http://www.nice.org.uk/guidance/CG60)
7. NICE OTITIS MEDIA WITH EFFUSION IN UNDER 12s :SURGERY [https://www.nice.org.uk/guidance/cg60/chapter/1-Guidance#clinical-presentation](https://www.nice.org.uk/guidance/cg60/chapter/1-Guidance#clinical-presentation)
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<td>PROCEDURE/TREATMENT</td>
<td>10.1.14 - HYSTERECTOMY FOR MENORRHAGIA (HEAVY MENSTRUAL BLEEDING, HMB). OSCAR REF: PA 14 05/2017</td>
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This commissioning policy is needed in order to clarify the criteria for referral for a hysterectomy for the treatment of menorrhagia.

### ELIGIBILITY CRITERIA

The CCGs do not commission Hysterectomy as a first line treatment for HMB in line with NICE guidance. [https://www.nice.org.uk/guidance/CG44/chapter/Recommendations#choice](https://www.nice.org.uk/guidance/CG44/chapter/Recommendations#choice)

Therefore, Hysterectomy for HMB will only be supported if other treatment options have failed or are contraindicated as outlined in NICE guidance [Clinical Guidance CG44: Heavy Menstrual Bleeding: assessment and management: published January 2007: updated August 2016]

This means for women with fibroids of <3cm or no structural abnormality and history and examination deem that pharmaceutical treatment is appropriate and either hormonal or non-hormonal treatments are acceptable then at least 2 pharmaceutical options should be explored in the following order:

- levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (at least 12 months) use is anticipated, and has been trialled for at least 6 cycles
- tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives (COCs)
- norethisterone (15 mg) daily from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens.
- If hormonal treatments are not acceptable to the woman, then either tranexamic acid or NSAIDs can be used.
- Endometrial ablation can be considered as initial treatment if the HMB is having a severe impact on the quality of life and the patient does not wish to conceive and after full discussion of benefits and risks of other treatment options with the patient or after failure of pharmaceutical measures.
- In women with no structural abnormality or fibroids <3cm and a uterine size of less than a 10-week pregnancy, endometrial ablation is preferable to hysterectomy.

For women with HMB and with uterine fibroids of >3cm, pharmaceutical treatment should be considered if clinically appropriate as above. Additional pharmaceutical options recommended by NICE for women with large fibroids > 3cm include the following:

- Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of...
• Consider ulipristal acetate 5 mg (up to 4 courses) [5] for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre
• In women with HMB and fibroids >3cm, Surgical intervention should be considered if HMB is having a severe impact on quality of life and there are associated significant symptoms including pressure symptoms or dysmenorrhea.
• When surgery is being considered for fibroid related HMB then all surgical options of uterine artery embolization, myomectomy and hysterectomy should be considered and women should be advised of the benefits and risks associated with all methods.
• In Secondary Care, appropriate pre-operative investigation and assessment [including with USS and MRI where appropriate] should be undertaken and pre-surgical treatment with GNRH analogues given where clinically appropriate.

Note:
• Endometrial ablation is suitable for women who do not want to conceive in the future and should only be offered after full discussion of risks and benefits and other treatment options
• For contra-indications to LNG-IUS please refer to manufacturers SPC guidance and FSRH guidance on the use if intra-uterine devices
• Use of a gonadotrophin-releasing hormone analogue could be considered by secondary care prior to surgery or when all other treatment options for uterine fibroids, including surgery or uterine artery embolisation, are contraindicated. If this treatment is to be used for more than 6 months or if adverse effects are experienced then hormone replacement therapy (HRT) 'add-back' therapy is recommended

Note: Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)
• Obesity - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications
with obesity and the risk to delaying any surgery.

- **Smoking** - In line with 'Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

### Summary of evidence / rationale

Hysterectomy is a major operation and is associated with significant complications in a minority of cases\(^1\). Since the 1990s the number of hysterectomies has been decreasing rapidly and it should not be used as a first-line treatment solely for HMB. There are now a range of alternative treatment options for HMB

**NICE clinical guidelines (2007)\(^1\)** emphasise that:

- The Mirena® device is effective in the treatment of menorrhagia and is considerably cheaper than a hysterectomy, even if required for many years (for contraception costs estimated at £207 including consultation; removal cost £26) and the fertility of the woman may be maintained. In a NICE study of long-acting reversible contraception, the average annual cost of Mirena was estimated at £70. This compares to the average cost to the CCG of performing a hysterectomy of £2,362.
- Other effective conservative treatments are available as second line treatment after failure of Mirena or where Mirena is contra-indicated

A Cochrane systemic review showed that the Mirena® coil improved the quality of life of women with menorrhagia as effectively as hysterectomy (no ref provided)

**Hysterectomy should be considered only when\(^1\):**

- All other treatment options have failed, are contraindicated or are declined by the woman
- there is a wish for amenorrhoea
- the woman (who has been fully informed) requests it
- the woman no longer wishes to retain her uterus and fertility.

The supporting evidence is given in more detail in the evidence reviews and statements from the clinical guidelines on Heavy menstrual bleeding given below\(^1,2\). For details of the primary studies and systematic reviews that NICE used to make their recommendations and a full bibliography, see their full guideline at [www.nice.org.uk](http://www.nice.org.uk).

### Date effective from

16th May 2017
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<td><strong>Author</strong></td>
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| **Clinical Reviewers** | GP NHS Wakefield CCG  
Consultant Gynaecology / Obstetrics, Mid Yorkshire Hospital Trust |
| **Approved by**   | Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG) |
| **Responsible Officer** | Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
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<td>PROCEDURE/TREATMENT</td>
<td>10.1.15 - HYSTERO SCOPY AND DILATION AND CURETTAGE IN MANAGEMENT OF HEAVY MENSTRUAL BLEEDING OSCAR REF: PA15 05/2017</td>
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Dilation and curettage (D&C) is a procedure performed under general anaesthetic in which the lining of the uterus (the endometrium) is biopsied or removed by scraping (curettage).

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<th>ELIGIBILITY CRITERIA</th>
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| • The CCGs will commission the use of hysteroscopy in the management of Heavy Menstrual Bleeding [HMB] in line with NICE guidance [CG44].  
• The CCGs will not commission the use of dilation and curettage [D&C] in the management of HMB which is in line with NICE Guidance [CG44]. |

**Hysteroscopy in management of HMB**
Patients will undergo hysteroscopy in the investigation and management of heavy menstrual bleeding only:

- When it is carried out as an investigation for structural and histological abnormalities where ultrasound has been used as a first line diagnostic tool and where the outcomes are inconclusive, for example to determine the exact location of a fibroid or the exact nature of the abnormality;
- Where dilatation is required for non-hysteroscopic ablative procedures, hysteroscopy should be considered immediately prior to the ablative procedure to ensure correct placement of the device.

**D&C**
NICE guidance recommends that D&C is NOT used

- as a diagnostic tool for heavy menstrual bleeding
- as a therapeutic treatment for heavy menstrual bleeding.


**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with 'Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

| Summary of evidence / rationale | Ultrasound (1st line) or hysteroscopy [with or without biopsy] (2nd line) are recommended as diagnostic techniques to investigate uterine bleeding disorders\(^1, 2, 3\) NICE guidance indicates that D&C alone should not be used for diagnostic purposes.

Hysteroscopy with biopsy is also the preferred technique to remove polyps and other benign lesions, as it allows targeted removal. If a tissue sample is required and there is no lesion visible on a scan then an endometrial biopsy may be done (using a small hollow plastic tube that removes a small plug of tissue on gentle suction).

There is limited evidence on the effectiveness of D&C in the management of menorrhagia. The one study identified by NICE showed that any effect was temporary\(^4\). NICE guidance states that D&C should not be used as a therapeutic treatment.

Evacuation of retained products of conception (ERPC): where surgical evacuation after incomplete miscarriage or delivery is clinically indicated over medical management and watchful waiting, vacuum aspiration has superseded D&C as it is quicker, safer, easier and less painful.

Gestational trophoblastic disease: Suction/vacuum curettage is the preferred method of evacuation irrespective of uterine size in patients with suspected hydatidiform mole who want to preserve fertility. |

| Date effective from | 16th May 2017 |
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| Clinical Reviewers         | GP NHS Wakefield CCG  
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| Responsible Officer      | Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
|                          | NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
| References               | 1. Investigation of Post-Menopausal Bleeding. SIGN Publication No 61; 2002. [http://www.nordhaven.co.uk/postmenopausalbleeding.PDF](http://www.nordhaven.co.uk/postmenopausalbleeding.PDF)  
|                          | 3. NICE Heavy menstrual bleeding January 2007 Do not do – D&C alone should not be used as a diagnostic tool [https://www.nice.org.uk/guidance/cg44](https://www.nice.org.uk/guidance/cg44)  
|                          | 4. NICE Heavy menstrual bleeding January 2007 Do not do – D&C should not be used as a therapeutic treatment [https://www.nice.org.uk/guidance/cg44](https://www.nice.org.uk/guidance/cg44)  

### POLICY STATEMENT

| COMMISSIONING POLICY |

### STATUS

| CRITERIA LED or PRIOR APPROVAL REQUIRED |

### PROCEDURE/TREATMENT

| 10.1.16 - ELECTIVE EYE SURGERY FOR THE TREATMENT OF CATARACTS IN ADULTS |

| OSCAR REF: PA16 05/2017 |

### Current DVLA guidance states that the minimum eyesight standard for driving is a Best Corrected Visual Acuity (BCVA) of at least 6/12 measured on the Snellen scale (with glasses or contact lenses, if necessary) using both eyes together (or, in the only eye, if monocular)

Referrals should not be based simply on the presence of a cataract. Cataract surgery should, therefore, not normally be offered to patients with a visual acuity better than 6/12 in the better eye. This applies to both first and second eye surgery.

Patients with the following symptoms or clinical conditions may benefit from cataract surgery when their visual acuity in the worse eye is 6/12 or worse. This list is not exhaustive:

1. Patients experiencing significant glare and dazzle in daylight or difficulties with night vision when these symptoms are due to lens opacities. This indication applies particularly, but not exclusively, to driving.
2. Patients requiring particularly good vision for employment purposes.
3. Difficulty with reading due to lens opacities
4. Significant optical imbalance (anisometropia or aniseikonia) following cataract surgery on the first eye.
5. Management of co-existing other eye conditions.
6. Refractive error primarily due to cataract.

### EXCLUSIONS

Where URGENT referral via existing diabetic retinal screening pathway is required

### ELIGIBILITY CRITERIA

Before a referral is made, the referrer must confirm that:

- The patient understands that the purpose of referral is for assessment for surgery.
- The patient wishes to have surgery if it is offered.
- The patient meets the criteria for cataract surgery.
- Cataract surgery will be routinely commissioned only in the following circumstances:
  - There is sufficient cataract in the eye proposed for surgery to account for the patient's visual symptoms

AND one or more of the following criteria apply:
Best corrected visual acuity of 6/12 or worse in the affected eye AND the patient experiences one or more of the following due to subjective loss of visual performance:

- Difficulty in accomplishing everyday tasks
- Reduced mobility, visual problems when driving or experiencing difficulty with steps or uneven ground.
- Ability to work, act as a carer or live independently is affected.
- Patients who experience disabling problems with glare and a reduction in acuity in daylight or bright conditions or reduced contrast sensitivity.
- The patient has a best corrected visual acuity of better than 6/12 in the affected eye but they are working in an occupation in which visual acuity better than 6/12 is essential to their ability to continue to work.
- Where there is anisometropia following cataract surgery with a refractive difference between the two eyes of at least +1.5 dioptres resulting in poor binocular vision or diplopia.
- Patients with rapidly progressive myopia.
- Cataract surgery is also routinely commissioned under the following circumstances:
  - Patients with glaucoma who require cataract surgery to control intra-ocular pressure.
  - Patients with glaucoma who have undergone a trabeculectomy.
  - Patients who have undergone a vitrectomy.
  - Patients with diabetes in whom removal of the cataract is necessary to facilitate effective screening for diabetic retinopathy.

Note: Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

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<tr>
<th>Summary of evidence / rationale</th>
<th>1. Introduction</th>
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<tr>
<td>Cataracts usually develop over a period of time, causing a gradual deterioration in eyesight. As it affects over a third of people aged over 65, cataract surgery continues to be the commonest elective procedure in day surgery performed in the UK. In the vast majority of cases the surgery involves local or topical anaesthesia, which markedly reduces operative and recovery time. Smoking and diabetes (associated with BMI &gt; 30) are further risk factors for cataract.</td>
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<td>80-90% of patients report a benefit from surgery, which include improved clarity of vision and improved colour vision. This in turn has implications for a positive</td>
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impact on other health and social care needs including a reduction in slips, trips and falls amongst the elderly.2

There are risks associated with cataract surgery, some common and many very rare; however, complications are usually treatable and reasonably good outcomes can be expected.

There is currently no widely validated Patient reported outcome measure (PROM) for cataract surgery. Based on a systematic review and study of cataract PROMs, the Catquest-9SF questionnaire currently appears to be the most promising instrument. Catquest-9SF has been validated in an English-speaking population (Australia), but has not yet been validated in the UK. A National Institute for Health Research (NIHR) applied cataract research programme is currently funded to develop a short form cataract PROM suitable for routine use in the NHS. This will help to identify from the patient's perspective whether surgery is currently being over or under provided.

2. Current guidance and thresholds
NICE recommendations for cataract surgery are not due until June 2017, but the Royal College of Ophthalmologists published guidelines on the management of cataract last year – although these may not cover all the issues from a commissioning perspective. Their guidelines recognise that “Visual acuity is the most common measurement of visual function as it can be quickly and easily measured” but goes on to point out that “the sole use of visual acuity can underestimate visual disability because it does not take account of symptoms such as glare or reduced contrast sensitivity.” This can, however, be hard to quantify objectively.

A best corrected visual acuity (BCVA) of better than 6/12 [Snellen], in the worse eye, normally allows a patient to function without significant visual difficulties. In population studies using BCVA as an indicator of morbidity, BCVA better than 6/12 is not considered a visually impairing cataract and acuity of 6/9 is considered a good outcome post-surgery. This applies to both first and second eye surgery.11

Significant improvements in visual symptoms and visual function may occur following cataract surgery even where the preoperative visual acuity is better than 6/12. However, the risk of worse visual acuity after surgery also increases where the preoperative visual acuity is very good, so surgery should be considered at this level of visual acuity only where the patient is experiencing significant symptoms attributable to cataract.2

3. Improving outcomes and cost-effectiveness
With such a common procedure, it is all the more important to seek
improvements in cost-effectiveness, both with patient selection and the actual procedure. There is no set level of vision for which an operation is essential. The rate at which cataracts progress is unpredictable. Reading glasses are usually needed after cataract surgery, and some people may require glasses for distance vision who did not previously require them.

With the current volume of cataract surgery and the increases in the future, it is critical to be able to optimise the safety, but also the cost effectiveness of this procedure. Most cataracts are age-related and therefore surgeries are performed on older individuals with correspondingly high systemic and ocular comorbidities. It is therefore more important to ensure the right balance of risk to benefit.

Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function.

Despite the lack of an evidence base to define thresholds both for initial referral to an ophthalmologist or for subsequent surgery, or to indicate cost-effectiveness, over-provision is recognised as a problem and thresholds are used to control access and resource use. A recent study found significant reductions in cataract surgery, among other “low priority” procedures, as part of NHS efforts to implement spending cuts.

Improvement in visual acuity has often been used to judge the outcome of surgery. Surveys have shown that in 1990, 9% of eyes had a pre-operative visual acuity of 6/12 or better. By 2009, this had risen to 43%. Thus with the large increase in procedures over the last 20 years, it would appear that eyes with better acuity are now being operated on. The potential for benefit, from a visual acuity point of view, therefore, is decreasing and the impact of surgery may be becoming less cost-effective.

There is good data now which shows the risk of worse visual acuity after surgery is significant if you operate in milder cases; so, there is a risk with overprovision of the threshold being too low.

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3. English National Health Service’s Savings Plan May Have Helped Reduce The Use Of Three ‘Low-Value’ Procedures Sophie Coronini-Cronberg et al Health Affairs March 2015 [http://content.healthaffairs.org/content/34/3/381.abstract](http://content.healthaffairs.org/content/34/3/381.abstract)


5. Evidence review: cataract surgery Hampson and Briggs; Cheshire West and Chester public health collaborative service May 2014

6. Sophie Coronini-Cronberg, member of Royal College of Ophthalmologists working group commissioned by NICE to develop commissioning guidelines (see ref 2) and Honorary Research Fellow, Department of Primary Care and Public Health, Imperial College London (personal communication) Cambridge and Peterborough CCG Cataracts policy March 2014.
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<tr>
<td>PROCEDURE/TREATMENT</td>
<td>10.1.17 - HERNIA REPAIR - INGUINAL (IN MEN), UMBILICAL, INCISIONAL</td>
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Hernia repair refers to a surgical operation for the correction of a hernia (a bulging of internal organs or tissues through the wall that contains it.) Hernias can occur in many places, including the abdomen, groin, diaphragm, brain, and at the site of a previous operation.

This statement covers surgical treatment of inguinal hernias in adult men, and umbilical or incisional hernias in all adults.

EXCLUSIONS

It EXCLUDES suspected femoral hernias, inguinal hernias in women, and any irreducible hernias, which should be referred urgently due to the increased risk of incarceration/strangulation.

ELIGIBILITY CRITERIA

An approach of watchful waiting is recommended for asymptomatic or minimally symptomatic abdominal hernias; watchful waiting is considered safe. Appropriate conservative management should also be tried first eg weight reduction or support from surgical appliances or underwear.

Surgical treatment should only be offered when one of the following criteria are met:

- Pain/discomfort interfering significantly with activities of daily living
- The hernia is difficult or impossible to reduce
- There is a risk of incarceration or strangulation of the bowel
- Comorbidity is present that will likely significantly in-crease the risks associated with surgery at a later date
- AND the patient has been a non-smoker for at least 8 weeks.


**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE:** Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)
**Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

**Smoking** - In line with 'Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

**Summary of evidence / rationale**

The Royal College of Surgeons 2013 - High Value Care Pathway for groin hernia (which includes a useful flow chart) states that GPs should refer:

- all patients with an overt or suspected inguinal hernia to a surgical provider except for patients with minimally symptomatic inguinal hernias who have significant comorbidity AND do not want to have surgical repair (after appropriate information provided)
- irreducible and partially reducible inguinal hernias, and all hernias in women as ‘urgent referrals’
- patients with suspected strangulated or obstructed inguinal hernia as ‘emergency referrals’
- all children <18 years with inguinal hernia to a paediatric surgical provider

Watchful waiting (WW) is regarded as an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias by the European Hernia Society guidelines on the treatment of inguinal hernia in adult patients (Level 1B evidence) and by a number of RCTs, concluding that it is an acceptable option for men with minimally symptomatic inguinal hernias. Delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely. More recently, the European Hernia Society has developed World Guidelines for Hernia Management which also supports this approach.


Analysis of 336 patients randomised to watchful waiting in the American College of Surgeons Watchful Waiting Hernia Trial found readily identifiable patient characteristics can predict those patients with minimally symptomatic inguinal hernia who are likely to "fail" watchful waiting hernia managements. These include pain with strenuous activities, chronic constipation and prostatism. Higher levels of activity reduced the risk of this combined outcome but there is no mention of BMI. Consideration of these factors will allow surgeons to tailor hernia management optimally.
Another study found that with follow up over 10 years, a total of 68% of men had had elective surgery, more commonly men older than 65 years, with pain. They conclude that, although WW is a reasonable and safe strategy, symptoms are likely to progress and an operation will be needed eventually. More recently a study concluded that a commissioning policy restricting funding for elective hernia repairs (but notably across all types) had led to a significant increase in emergency hernia repairs. They carried out a retrospective cohort study on around 2550 patients who underwent repair of inguinal, umbilical, incisional, femoral or ventral hernias over a 3-year period.

The number of elective hernia repairs reduced from 857 over 12 months before the funding restrictions to 606 in the same period afterwards (p < 0.001). Over the same time period, however, a significant rise in total emergency hernia repairs was demonstrated, increasing from 98 to 150 (p < 0.001). 30-day readmission rates also increased from 5.1 % before the policy introduction to 8.5 % afterwards (p = 0.006). They concluded that the funding restrictions introduced in 2011 were followed by a statistically significant and unintended increase in emergency hernia repairs in their trust, with associated increased risks to patient safety.

A “watchful waiting” approach is also supported by other CCGs, including the Leeds CCGs. Their clinical guidelines commissioning position is that hernia repair is not routinely commissioned for:
Men with an asymptomatic or a minimally symptomatic inguinal hernia (discomfort or pain that does not restrict daily activity - adopt watchful waiting)
Men with groin pain and an ultrasound detected, but clinically impalpable, hernia (consider musculo-skeletal referral)
Post-operative follows up for low risk cases (ie no evidence of clinically significant haematoma, injury to the bowel or major blood vessels, deep infection, ischaemic orchitis, recurrence)

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**POLICY STATEMENT**

COMMISSIONING POLICY

**STATUS**

CRITERIA LED or PRIOR APPROVAL REQUIRED

**PROCEDURE/TREATMENT**

10.1.18 - THE REFERRAL AND SPECIALIST MANAGEMENT OF HAEMORRHOIDS IN ADULTS

OSCAR REF: PA18 05/2017

Haemorrhoids are enlarged vascular cushions in the anal canal and may be external or internal. They are the commonest cause of rectal bleeding.

Definition of degrees of haemorrhoids:

- First grade: the haemorrhoids remain inside at all times
- Second grade: the haemorrhoids extend out of the rectum during a bowel movement but return on their own
- Third grade: the haemorrhoids extend out during a bowel movement but can be pushed back inside
- Fourth grade: the haemorrhoid is always outside

**EXCLUSIONS**

Consider referral for patients with:

- Refer using the suspected cancer pathway referral (for an appointment within 2 weeks) if anal or colorectal cancer is suspected. See the CKS topic on Gastrointestinal tract (lower) cancers - recognition and referral for detailed information on when to suspect anal or colorectal cancer.
- Extremely painful, acutely thrombosed external haemorrhoids who present within 72 hours of onset (reduction or excision may be needed).
- Internal haemorrhoids that have prolapsed and become swollen, incarcerated, and thrombosed (haemorrhoidectomy may be needed).
- Perianal sepsis (a rare but life-threatening complication).
- Refer to an appropriate specialist (using clinical judgement to determine the urgency) if another serious pathology, such as inflammatory bowel disease or a sexually transmitted infection, is suspected.

**ELIGIBILITY CRITERIA**

Referral for non-urgent assessment and treatment

Referral for specialist assessment and treatment of haemorrhoids is not routinely commissioned by the CCGs and will only be funded if:

- The haemorrhoids are prolapsed and incarcerated, and cannot be reduced (Fourth degree haemorrhoids) OR
- The haemorrhoids are recurrent and associated with persistent bleeding
- AND there is failure of documented conservative management techniques after at least three months.

**Conservative management techniques include:**

- Dietary and lifestyle advice (increase fluid and insoluble fibre intake, discourage straining)
- Bulk forming laxative (or osmotic laxative or stool softener)
- Non-opioid analgesia and/or topical haemorrhoid preparations for symptomatic
relief.

**Non-surgical treatment**
- Non-surgical measures (rubber band ligation, injection sclerotherapy or infra-red coagulation) will only be commissioned in the following circumstances
  - **Recurrent haemorrhoids with** Persistent bleeding AND
  - Failure of documented conservative management techniques after at least three months.

**Surgical treatment**
Surgical treatment (haemorrhoidectomy, stapled haemorrhoidopexy or haemorrhoidal artery ligation) will only be commissioned in the following circumstances:
- Fourth-degree haemorrhoids
- Third-degree haemorrhoids associated with persistent bleeding that have not responded to non-surgical treatment in line with the above policy statement, or which are too large for non-surgical measures
- Second-degree haemorrhoids associated with persistent bleeding that have not responded to non-surgical treatment in line with the above policy statement

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<p>| Summary of | There is some evidence of longer term efficacy of conventional |</p>
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<thead>
<tr>
<th>evidence / rationale</th>
<th>haemorrhoidectomy over stapled procedure.</th>
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<tr>
<td></td>
<td>Short term efficacy and cost effectiveness is similar.</td>
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<tr>
<td></td>
<td>Stapled haemorrhoidopexy for the treatment of haemorrhoids&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>Technology appraisal guidance [TA128]Published date: 26 September 2007</td>
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<td>BMJ Clinical Review&lt;sup&gt;2&lt;/sup&gt; - Management of haemorrhoids BMJ2008; 336 doi: <a href="http://dx.doi.org/10.1136/bmj.39465.674745.80">http://dx.doi.org/10.1136/bmj.39465.674745.80</a> (Published 14 February 2008) Cite this as: BMJ 2008;336:380</td>
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<td>American Society of Colon and Rectal Surgeons&lt;sup&gt;5&lt;/sup&gt; Practice parameters for the management of hemorrhoids (revised 2010). Jama Surgery&lt;sup&gt;4&lt;/sup&gt;</td>
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<td>Long-term Outcomes of Stapled Hemorrhoidopexy vs Conventional Hemorrhoidectomy A Meta-analysis of Randomized Controlled Trials Pasquale Giordano, MD, FRCS, FRCS; Gianpiero Gravante, MD; Roberto Sorge, PhD; Lauren Ovens, MBChB, MRCS; Piero Nastro, MD, MRCS Arch Surg. 2009;144(3):266-272. doi:10.1001/archsurg.2008.591.</td>
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<td>NICE Clinical Knowledge Summaries&lt;sup&gt;6&lt;/sup&gt;</td>
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<tr>
<td>Clinical Reviewers</td>
<td>GP NHS Wakefield CCG Surgeon, Mid Yorkshire Hospital Trust</td>
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<td>2. BMJ Clinical Review - Management of haemorrhoids <a href="http://www.bmj.com/content/336/7640/380">http://www.bmj.com/content/336/7640/380</a></td>
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### Policy Statement

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<tr>
<th>POLICY STATEMENT</th>
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<tr>
<td>STATUS</td>
<td>CRITERIA LED or PRIOR APPROVAL REQUIRED</td>
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<tr>
<td>PROCEDURE/TREATMENT</td>
<td>10.1.19 - UPRIGHT/OPEN/WIDE BORE MRIs OSCAR REF: PA 19 05/2017</td>
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Current uMRI scanners generally use medium field magnets of 0.5T or 0.6T. uMRI here refers to any system of 0.5T or greater that allows for scanning in various positions, regardless of manufacturer. By comparison, the most advanced standard rMRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, uMRI requires more time to obtain images with lower resolution.

Slower imaging times with uMRI may create difficulty for patients who are unable to remain still while in a standing or sitting position; not comfortable secondary to pain; or are unstable in such positions. Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated.

The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement. It is theorized that such positional imaging may provide information not available from methods currently used (i.e. supine conventional MRI) and that this added information will lead to improved diagnosis, treatment and outcomes.

### Exclusions

<table>
<thead>
<tr>
<th>EXCLUSIONS</th>
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<tbody>
<tr>
<td>Referral for Open MRI scanning of at least 0.5T as an alternative to conventional MRI may be commissioned in the following circumstances as an exception where the following criteria is met:</td>
</tr>
<tr>
<td>- Patients who suffer from claustrophobia where an oral prescription sedative has not been effective (flexibility in the route of sedative administration may be required in paediatric patients as oral prescription may not be appropriate). For the use for Spinal cord compression and neural axis tumours. The use of Open MRI is recommended rather than the use of a general anaesthetic as there is a lesser risk to the patient.</td>
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<tr>
<td>- Patients who are obese and cannot fit comfortably in conventional MRI scanners as determined by a Radiology department policy. (The issue re size is how the weight is distributed).</td>
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<td>- patients who cannot lie properly in conventional MRI scanners because of severe pain</td>
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<td>- And the purpose of the scan is a last resort to exclude larger lesions if this is clinically relevant in the brain and spine. Peripheral body parts will not normally be considered for upright MRI unless at the specific request of an acute consultant who believes this is essential to clinical management due to failed trial of single body part MRI.</td>
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</table>
- And The patient is registered with the GP Practice
- IN ADDITION, The CCGs will only fund uMRI of the specific anatomy requested.

**Note:** Funding for patients not meeting the above criteria will only be made available in clinically exceptional circumstances. For those patients who are not eligible for treatment under this policy, will 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 via the CCGs Prior Approval Process. (Appendix 2 - Prior Approval Funding Request Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<th>Summary of evidence / rationale</th>
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<td>GP NHS North Kirklees CCG</td>
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<td>National Clinical Manager and Regional Clinical Lead, Connect Health</td>
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5. ACR PRACTICE GUIDELINE FOR PERFORMING AND INTERPRETING MAGNETIC RESONANCE IMAGING (MRI). Revised 2011.
   http://www.acr.org/~/media/EB54F56780AC4C6994B77078AA1D6612.pdf accessed July 2013


19. Hailey D. Open magnetic resonance imaging (MRI) scanners. Issues in Emerging Health Technologies. Issue 92. Ottawa, Canada; Canadian Agency for Drugs and Technologies in Health (CADTH); 2006.


10.2 Procedures that require Individual Funding Approval:

### Aesthetic (Cosmetic) Procedures (10.2.1 – 10.2.24)

<table>
<thead>
<tr>
<th>Procedure</th>
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<tbody>
<tr>
<td>Abdominoplasty (“Tummy Tuck”)</td>
<td>10.2.1</td>
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<tr>
<td>Breast Augmentation</td>
<td>10.2.2</td>
</tr>
<tr>
<td>Breast Reduction</td>
<td>10.2.3</td>
</tr>
<tr>
<td>Breast Asymmetry</td>
<td>10.2.4</td>
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<tr>
<td>Breast Reduction for Gynaecomastia (Male)</td>
<td>10.2.5</td>
</tr>
<tr>
<td>Breast Lift (Mastopexy)</td>
<td>10.2.6</td>
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<tr>
<td>Nipple Inversion</td>
<td>10.2.7</td>
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<tr>
<td>Hair Removal</td>
<td>10.2.8</td>
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<tr>
<td>Correction of Male Pattern Baldness</td>
<td>10.2.9</td>
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<tr>
<td>Hair Transplantation</td>
<td>10.2.10</td>
</tr>
<tr>
<td>Acne Scaring</td>
<td>10.2.11</td>
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<tr>
<td>Benign Skin Lesions</td>
<td>10.2.12</td>
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<tr>
<td>Blepharoplasty</td>
<td>10.2.13</td>
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<tr>
<td>Body Contouring Procedures (Buttock, Thigh and Arm Lift Surgery)</td>
<td>10.2.14</td>
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<tr>
<td>Congenital Vascular Abnormalities</td>
<td>10.2.15</td>
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<tr>
<td>Correction of Prominent Ears</td>
<td>10.2.16</td>
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<tr>
<td>Facelift</td>
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<tr>
<td>Labiaplasty</td>
<td>10.2.18</td>
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<tr>
<td>Liposuction</td>
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<td>Rhinoplasty</td>
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<tr>
<td>Rhinophyma</td>
<td>10.2.21</td>
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<tr>
<td>Surgical Scars</td>
<td>10.2.22</td>
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<tr>
<td>Thread Veins/Telangectasias</td>
<td>10.2.23</td>
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<tr>
<td>Tattoo Removal</td>
<td>10.2.24</td>
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<tr>
<td>Reversal of Vasectomy and Female Sterilisation</td>
<td>10.2.25</td>
</tr>
<tr>
<td>Fertility Services</td>
<td>10.2.26</td>
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<tr>
<td>Surrogacy</td>
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<tr>
<td>Lycra Garments</td>
<td>10.2.28</td>
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<tr>
<td>Functional Electrical Stimulation (FES) Policy for Foot Drop of Central Neurological Origin</td>
<td>10.2.29</td>
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<tr>
<td>Spinal Injections (Therapeutic) for Pain Related to the Lumbar Spine</td>
<td>10.2.30</td>
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<td>STATUS</td>
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</table>
| PROCEDURE/TREATMENT | 10.2.1 ABDOMINOPLASTY  
OSCAR REF: IFR1 05/2017 |
| ELIGIBILITY CRITERIA | Abdominoplasty will not be routinely commissioned by the CCGs for requests made for:  
- cosmetic/aesthetic reasons, including stretch marks  
- Psychological benefit without associated clinical need |
|                  | Abdominoplasty may rarely be considered on an exceptional basis, for example where the patient:  
- Has achieved a significant amount of weight loss (moved down two levels of the BMI SIGN guidance)  
- Have a stable BMI (stable is defined as within the acceptable range for at least 2 years) between 18.5 and 27 Kg/m²  
- AND be suffering from severe functional problems: is experiencing severe difficulties with daily living, for example ambulatory or urological restrictions  
- Those with complex scarring following trauma or previous abdominal surgery  
- Those who have undergone treatment for morbid obesity and have excessive skin folds  
- Previously obese patients who have achieved significant weight loss and have maintained their weight loss for at least two years.  
- Where it is required as part of abdominal hernia correction or other abdominal wall surgery |
|                  | Severe functional problems include:  
- Recurrent intertrigo beneath the skin fold.  
- Experiencing severe difficulties with daily living, i.e. ambulatory restrictions  
- Where previous post-trauma or surgical scarring (usually midline vertical or multiple) leads to very poor appearance and carries a risk of infection  
- Problems associated with poorly fitting stoma bags |
|                  | **In addition to this criterion and support the IFR, also require:**  
- BMI to have been measured within 2 months of the request being submitted |
|                  | **Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form) |
NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>PROCEDURE/ TREATMENT</td>
<td>10.2.2 - BREAST AUGMENTATION (BREAST ENLARGEMENT) OSCAR REF: IFR2 05/2017</td>
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| ELIGIBILITY CRITERIA | Note: Breast enlargement which is part of reconstructive surgery after trauma or previous mastectomy or other excisional breast surgery does not go through the Individual Funding requests process as it is part of the treatment pathway for those conditions.  
  
Breast augmentation will not be routinely commissioned by the NHS for:  
- Cosmetic reasons, for example for small normal breasts or for breast tissue involution (including post-partum changes).  
- Requests made for psychological benefit without associated clinical need.  

Breast augmentation may rarely be considered on an exceptional basis, for example where the patient:  
- has a complete absence of breast tissue either unilaterally or bilaterally or  
- has suffered trauma to the breast during or after development and  
- has a BMI within the range 18.5 – 27 and  
- has completed puberty as surgery is not routinely commissioned for individuals who are below 19 years of age  
- Patients who have received feminising hormones for an adequate length of time as part of a recognised treatment programme for gender dysphoria will only be considered when they meet the above criteria.  
- Revision surgery will only be commissioned for implant failure or for other physical symptoms, for example capsule contracture associated with pain, and not for aesthetic indications.  
- Implant replacement will only be considered if the original procedure was performed by the NHS.  

Note: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)  

NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)  
- Obesity - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to
address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
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<td>PROCEDURE/TREATMENT</td>
<td>10.2.3 - BREAST REDUCTION (Also known as surgery for breast hypertrophy or reduction mammoplasty.)</td>
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<tr>
<td>OSCAR REF: IFR3 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Breast reduction will not routinely be commissioned by the NHS for cosmetic reasons.</td>
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<tr>
<td></td>
<td>Breast reduction may rarely be considered on an exceptional basis, for example where the patient:</td>
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<td>• has a breast measurement of cup size G or larger and</td>
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<td>• has a BMI of less than 30 kg/m²</td>
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<td>• is 19 years of age or over</td>
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<td>• has significant musculo-skeletal pain causing functional impairment which in the opinion of the referrer is likely to be corrected or significantly improved by surgery</td>
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<td>• has tried and failed with all other advice and support, including a professional bra fitting and assessment by a physiotherapist where relevant</td>
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<tr>
<td>In addition to this criterion and support the IFR, also require:</td>
<td>• That patient has had a physiotherapy assessment carried out within 6 months of the request being made. The report must be sent with the request and must clearly give an opinion as to the cause of the patient’s pain. No request for funding can be considered without a recent physiotherapy report.</td>
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<td>• Written confirmation of a professional bra fitting being done in the last 6 months</td>
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<td>• BMI to have been measured within 2 months of the request being submitted</td>
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<td>• The patient is aged 19 years or over, to allow for the completion of normal development</td>
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| NB: For WCCG Patients: Body Image Scanner | The IFR Team will check the details in the referral are in line with the criteria outlined above - this is purely to ensure that patients are not rejected later for obvious reasons- if the patient meets the criteria, their details will be forwarded to Body Aspect Limited and the GP informed of this. If a patient does not meet the criteria a letter will be returned to the GP explaining that they are unsuitable for referral to the scanner and that if the patient and GP wish to proceed with a request for breast reduction surgery they will need to put an exceptional case
together to be considered at ECP. The patients who have met the criteria, are authorised for a scan and had their details passed on, will be contacted by Body Aspect Limited and an appointment date and time agreed for them to be scanned at Nottingham. Once the patient has been scanned a report will be produced and sent to the IFR Team, who will assess the patient's report against the eligibility criteria. In summary, these criteria are:

- Ratio of breast size to torso
- BMI of 30 or less*

*Patients will be refused a body scan if their BMI exceeds 30 on the day of scanning; referring clinicians should counsel patients regarding this as weight can fluctuate throughout the month and they will need to ensure their BMI is below 30.

Breast reduction surgery will be provided by the NHS if the following criteria are met:

- Patient must have met the initial conditions at the GP assessment
- The patient must have a BMI of 30 or less to undergo body scan
- Breast volume is equal or larger than 1000cc per breast (determined by body scan)
- Breast to torso ratio: The ratio of combined breast volume to adjusted partial torso volume is equal or greater than 13%. The ratio of 13% has been determined by using sample patients and clinical judgment of plastic surgeons in developing these criteria within the Nottingham area (determined by body scan).

Outcomes
There are three likely outcomes from the assessment:

- Patient meets all the criteria
- Patient ineligible for scan due to BMI of greater than 30
- Patient does not meet the criteria

Each of these three outcomes leads to different management on the pathway:

a) If the patient meets all the criteria, the IFR Team will receive a report following the scan assessment supporting the referring clinician and patient's request for breast reduction surgery. The IFR Team will then advise the patient's GP in writing that the patient meets the eligibility criteria to progress to surgery without the need for consideration by the ECP. The GP can then make a referral to an agreed provider attaching the results from the body scan assessment and the authorisation letter from the IFR Team. The body scan will be used by the surgeon as part of the pre-treatment counselling with the patient, to assess final outcome. It will also be used during surgery to determine the volume of tissue to be removed from each breast.

b) If the patient is ineligible for scan due to BMI greater than 30, the IFR Team will advise the patient's GP in writing of the outcome of the assessment- that the patient did not receive a scan due to ineligibility. Further intervention e.g. weight management support may enable patient to fulfil the necessary criteria and the patient may be re-referred to Body Aspect Limited for a scan at a subsequent time.
c) Patient does not meet breast volume and/or breast torso ratio criteria (identified in the eligibility criteria above). The IFR Team will receive a report detailing why the patient failed against the criteria following the scan assessment, and is therefore ineligible for breast reduction surgery. The IFR Team will then pass this information on to the patient and GP. At this point the GP, through discussion with his patient, may wish to put a case to the ECP. However, they will need to provide strong supporting clinical information for a case to be successful if the patient has failed the eligibility criteria above.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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Surgery to correct breast asymmetry will not routinely be commissioned by the NHS for cosmetic reasons.

Surgery may rarely be considered on an exceptional basis, for example where the patient:
- has a difference of at least 2 cup sizes
- has a BMI in the range 18.5 - 27
- has tried and failed with all other advice and treatment, including a professional bra fitting
- has completed puberty - surgery is not normally commissioned below the age of 19 years

National supporting evidence

In addition to this criterion and support the IFR, also require:
- Evidence supplied by a professional bra fitter that there is a difference in breast size of at least 2 cup sizes difference.

Note: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to
encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<pre><code>                   | NHS North Kirklees CCG &amp; NHS Wakefield CCGs GP Leads Planned Care |
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<td>PROCEDURE/TREATMENT</td>
<td>10.2.5 - BREAST REDUCTION FOR GYNAECOMASTIA (MALE) OSCAR REF: IFR5 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Surgery to correct gynaecomastia will not routinely be commissioned by the NHS for cosmetic reasons. Surgery may be considered on an exceptional basis, for example where the patient: • has more than 100g of sub areolar gland and ductal tissue (not fat) and • has a BMI of less than 25 • has been screened prior to referral to exclude endocrinological and drug related causes or if drugs have been a factor then a period of one year since last use should have elapsed • has completed puberty - surgery is not routinely commissioned below the age of 19 years • has been monitored for at least 1 year to allow for natural resolution if aged 25 or younger</td>
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National supporting evidence

In addition to this criterion and support the IFR, also require:
• BMI to have been measured within 2 months of the request being submitted
• Evidence that screening for endocrine and drug-related causes has taken place and their results

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE**: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)
• **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to
address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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### PROCEDURE/TREATMENT

10.2.6 - BREAST LIFT (MASTOPEXY)
OSCAR REF: IFR6 05/2017

### ELIGIBILITY CRITERIA

Mastopexy will not be routinely commissioned by the NHS for cosmetic reasons, for example post lactation or age-related ptosis. This may be included as part of the treatment to correct breast asymmetry and reduction.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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16th May 2017

### Date published

FINAL 12th May 2017

### Review date

April 2018 or when new NICE Guidance is available

### Author

Interim Planned Care Lead, NHS North Kirklees & NHS Wakefield CCG

### Clinical Reviewers

GP NHS North Kirklees CCG  
National Clinical Manager and Regional Clinical Lead, Connect Health

### Approved by

Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG)

### Responsible Officers

Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care
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| PROCEDURE/TREATMENT | 10.2.7 - NIPPLE INVERSION  
OSCAR REF: IFR7 05/2017 |
|---------------------|--------------------------|

| ELIGIBILITY CRITERIA | Surgical correction of benign nipple inversion will not be routinely commissioned by the NHS for:  
- Requests made for cosmetic/aesthetic reasons.  
- Requests made for psychological benefit without associated clinical need. |

Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded. The criteria are:  
- Surgical correction of nipple inversion should only be available for functional reasons in a post-pubertal woman and if the inversion has not been corrected by correct use of a non-invasion suction device.  

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**  
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.  
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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| PROCEDURE/TREATMENT | 10.2.8 - HAIR REMOVAL  
OSCAR REF: IFR 8 05/2017 |
| ELIGIBILITY CRITERIA | Hair removal will not be routinely commissioned by the NHS for cosmetic reasons.  
Hair removal may be considered on an exceptional basis, for example where the patient:  
- has undergone reconstructive surgery resulting in abnormally located hair bearing skin  
- has a proven underlying endocrine disturbance resulting in hirsutism (e.g. polycystic ovary syndrome)  
- Are undergoing treatment for pilonidal sinuses to reduce recurrence |

**In addition to this criterion and support the IFR, also require:**
- Evidence of the underlying endocrine disturbance
- Where laser treatment is requested for hair removal and the applicant meets the above criteria up to 10 sessions will be approved at any one time. Following those 10 sessions the referring clinician will be asked to write to the CCG with evidence of effectiveness before any further treatment can be approved.
- Where laser treatment for hair removal is requested for hirsutism it will only be approved for the removal of facial hair

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice** (This is not a restriction to this policy unless otherwise stated)
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of
There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>PROCEDURE/TREATMENT</td>
<td>10.2.9 - CORRECTION OF MALE PATTERN BALDNESS OSCAR REF: IFR9 05/2017</td>
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<td>ELIGIBILITY CRITERIA</td>
<td>Treatments to correct male pattern baldness will not be routinely commissioned by the NHS for cosmetic reasons. This is excluded from treatment by the NHS. <strong>Note</strong>: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)</td>
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**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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Responsible Officers | Interim Chief Operating Officer, North Kirklees & Wakefield CCG |
| NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
ELIGIBILITY CRITERIA

Hair transplantation will not be routinely commissioned by the NHS for cosmetic reasons, regardless of gender.

Hair transplantation may be considered on an exceptional basis, for example when reconstruction of the eyebrow is needed following cancer or trauma.

Note: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>PROCEDURE/ TREATMENT</td>
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<td>OSCAR REF: IFR11 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Procedures to treat facial acne scarring will not be routinely commissioned by the NHS.</td>
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Cases may be considered on an exceptional basis, for example when the patient has very severe facial scarring unresponsive to conventional medical treatments.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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**Responsible Officers**: Interim Chief Operating Officer, North Kirklees & Wakefield CCG
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care
Surgical treatment of benign skin lesions will not be routinely commissioned by the NHS for cosmetic reasons.

Cases may be considered on an exceptional basis, for example when:
- lesions are visible on hands or face and of considerable size
- Lesions are causing significant physical symptoms or impairment.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with 'Healthy Lives, Healthy People; a tobacco control plan for England', local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>PROCEDURE/TREATMENT</td>
<td>10.2.13 – BLEPHAROPLASTY (Surgery for drooping or mis-shaped eyelid) OSCAR REF: IFR13 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Blepharoplasty will not be routinely commissioned by the NHS for cosmetic reasons</td>
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<td>Surgery on the upper lid maybe considered to correct functional impairment (not purely for cosmetic reasons) as demonstrated by:</td>
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<td>• Impairment of visual fields in the relaxed, non-compensated stable.</td>
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<td>• Clinical observation of poor eyelid function, discomfort, e.g. headache worsening towards end of day and/or evidence of chronic compensation through elevation of the brow.</td>
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<td><strong>NB. Evidence of the above will be required to support the request</strong></td>
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<td><strong>Note</strong>: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)</td>
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<td>• <strong>Obesity</strong> - Patients with a BMI &gt;30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.</td>
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<td>PROCEDURE/TREATMENT</td>
<td>10.2.14 – BODY CONTOURING PROCEDURES (BUTTOCK, THIGH AND ARM LIFT SURGERY) OSCAR REF: IFR14 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Surgery to remove excess skin from the buttock, thighs and arms will not be routinely commissioned by the NHS for cosmetic reasons. Cases may be considered on an exceptional basis, for example where the patient: • as an underlying skin condition, for example cutis laxa • has lost a considerable amount of weight resulting in severe mechanical problems affecting activities of daily living • has a normal BMI in the range 18.5 – 30 for a minimum of 2 years • In addition to this criterion and to support the IFR, also required: o BMI to have been measured within 2 months of the request being submitted</td>
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**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.
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<td>PROCEDURE/TREATMENT</td>
<td>10.2.15 – CONGENITAL VASCULAR ABNORMALITIES OSCAR REF: IFR15 05/2017</td>
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| ELIGIBILITY CRITERIA | Procedures for congenital vascular abnormalities will not be routinely commissioned by the NHS for cosmetic reasons. Cases may be considered on an exceptional basis for lesions of considerable size on exposed areas only.  

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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| Review date         | April 2018 |
| Author              | Interim Planned Care Lead North Kirklees &amp; Wakefield CCG |
| Clinical Reviewers  | N/A (Taken from existing Policies) |
| Approved by         | Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG) |
| Responsible Officers| Interim Chief Operating Officer, North Kirklees &amp; Wakefield CCG NHS North Kirklees CCG &amp; NHS Wakefield CCGs GP Leads Planned Care |</p>
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<td>PROCEDURE/TREATMENT</td>
<td>10.2.16 – CORRECTION OF PROMINENT EARS (“BAT EARS”) OSCAR REF: IFR16 05/2017</td>
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| ELIGIBILITY CRITERIA | Surgical correction of prominent ears will not be routinely commissioned by the NHS for cosmetic reasons. Cases may be considered on an exceptional basis, for example where the patient:  
• Must be aged 5-19 at the time of referral and the child (not the parents alone) expresses concern AND  
• has very significant ear deformity or asymmetry  

**National supporting evidence**  

Prominent ears may lead to significant psychosocial dysfunction for children and adolescents and impact on the education of young children as a result of teasing and truancy. The national service framework for children defines childhood as ending at 19 years. Some patients are only able to seek correction once they are in control of their own health care decisions.  

Children under the age of 5 rarely experience teasing and referral may reflect concerns expressed by the parents rather than the child.  

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

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| PROCEDURE/TREATMENT | 10.2.16 – FACELIFT  
OSCAR REF: IFR16 05/2017 |
| ELIGIBILITY CRITERIA | Facial procedures and Botulinum Toxin will not be routinely commissioned by the NHS for cosmetic reasons.  
Cases may be considered on an exceptional basis, for treatment of:  
- Congenital facial abnormalities  
- Facial palsy (congenital or acquired paralysis)  
- As part of the treatment of specific conditions affecting the facial skin, e.g. cuffs axa pseudoxanthoma elaticum, neurofibromatosis  
- To correct the consequences or trauma  
- To correct deformity following surgery.  
Note: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form) |
| NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated) |  
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.  
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing. |

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<td>OSCAR REF:</td>
<td>IFR18 05/2017</td>
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<td>ELIGIBILITY CRITERIA</td>
<td>Labiaplasty will not be routinely commissioned by the NHS for cosmetic reasons.</td>
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<td><strong>NB. Evidence of any severe functional problems must be provided if a funding request is submitted</strong></td>
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**STATUS** | CRITERIA LED REQUIRING INDIVIDUAL FUNDING REQUEST
**PROCEDURE/TREATMENT** | 10.2.19 – LIPOSUCTION  
OSCAR REF: IFR19 05/2017
**ELIGIBILITY CRITERIA** | Liposuction will not be routinely commissioned by the NHS for cosmetic reasons or to simply correct the distribution of fat.

Cases may be considered on an exceptional basis, for example when
- It may be useful for contouring areas of localised fat atrophy or pathological hypertrophy (e.g. multiple lipomatosis, lipodystrophies)
- if it is an adjunct to other surgical procedures e.g. surgery for gynaecomastia.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
**Policy Statement**

**Commissioning Policy**

**Status**

Criteria led requiring Individual Funding Request

**Procedure/Treatment**

10.2.20 – Rhinoplasty

OSCAR REF: IFR20 05/2017

**Eligibility Criteria**

Rhinoplasty will not be routinely commissioned by the NHS for cosmetic reasons. Cases may be considered on an exceptional basis, for example in the presence of:

- Problems caused by obstruction of the nasal airway
- Objective nasal deformity caused by trauma
- Correction of complex congenital conditions (e.g. cleft lip and palate)

**Note**: Post traumatic airway obstruction, septal deviation or correction of complex congenital conditions (e.g. cleft lip and palate) which are part of the treatment pathway for those conditions do NOT need funding approval.

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

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<td>PROCEDURE/TREATMENT</td>
<td>10.2.21 – RHINOPHYMA</td>
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<td>OSCAR REF: IFR21 05/2017</td>
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<td>ELIGIBILITY CRITERIA</td>
<td>Surgical/laser treatment of rhinophyma will not be routinely commissioned by the NHS for cosmetic reasons.</td>
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<td>The first-line treatment of this disfiguring condition of the nasal skin is medical. Severe cases or those that do not respond to medical treatment may be considered for surgery or laser treatment.</td>
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<td>ELIGIBILITY CRITERIA</td>
<td>Revision surgery for scars will not be routinely commissioned by the NHS for cosmetic reasons.</td>
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<td>Cases may be considered on an exceptional basis, for example where the patient:</td>
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<td>- has significant deformity, severe functional problems, or needs surgery to restore normal function</td>
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<td>- has a scar resulting in significant facial disfigurement.</td>
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<td>Treatment for thread veins and telangiectasia will not be routinely commissioned by the NHS for cosmetic reasons.</td>
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| ELIGIBILITY CRITERIA | Tattoo removal will not be routinely commissioned by the NHS. Cases may be considered on an exceptional basis, for example where the patient:  
- has suffered a significant allergic reaction to the dye and medical treatments have failed  
- where the tattoo is the result of trauma, inflicted against the patient’s will (“rape tattoo”)  
- exceptions may also be made for tattoos inflicted under duress during adolescence or disturbed periods where it is considered that psychological rehabilitation, break up of family units or prolonged unemployment could be avoided given the treatment opportunity. (Only considered in very exceptional circumstances where the tattoo causes marked limitations of psychosocial functioning.) |

**National supporting evidence**

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**
- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient
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Treatment for thread veins and telangectasia will not be routinely commissioned by the NHS for cosmetic reasons.

Note: Funding for patients will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)

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Clinical Reviewers N/A (Taken from existing Policies)

Approved by Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG)

Responsible Officers Interim Chief Operating Officer, North Kirklees & Wakefield CCG NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care
## COMMISSIONING POLICY

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<tr>
<td>PROCEDURE/ TREATMENT</td>
<td>10.2.25 – REVERSAL OF VASECTOMY AND FEMALE STERILISATION OSCAR REF: IFR25 05/2017</td>
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</table>

### ELIGIBILITY CRITERIA

Surgery for the Reversal of a Vasectomy or Female Sterilisation will not be routinely commissioned by the NHS. Cases may be considered on an exceptional basis, for example:

- the death of an existing child
- There is clear evidence (over and above the patient’s assertion) that the original operation had been performed under duress. e.g. Cases when the patient was very young when the procedure was carried out and evidence from the referring clinician shows that they did not receive any counselling.

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.
- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<td>Author</td>
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| **Responsible Officers** | Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
|-------------------------|------------------------------------------------------------------|


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</table>
| PROCEDURE/TREATMENT | 10.2.26 – IVF – INFERTILITY TREATMENT  
OSCAR REF: IFR26 05/2017 |
| ELIGIBILITY CRITERIA | Criteria has been agreed across the Yorkshire and Humber. See Appendix 7 – separate document to this policy.  
The CCGs arrangements are in line with the above policy but the CCGs will only fund one full cycle where the eligibility criteria are met. |
| Date effective from | 16th May 2017 |
| Date published | FINAL 12th May 2017 |
| Review date | April 2018 |
| Author | Interim Planned Care Lead North Kirklees & Wakefield CCG |
| Clinical Reviewers | N/A (Taken from existing Policies) |
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NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
POLICY STATEMENT | COMMISSIONING POLICY
---|---
STATUS | CRITERIA LED REQUIRING INDIVIDUAL FUNDNG REQUEST
PROCEDURE/TREATMENT | 10.2.27 – SURROGACY
OSCAR REF: IFR27 05/2017
ELIGIBILTY CRITERIA | Criteria has been agreed across the Yorkshire and Humber: See Appendix 7 – separate document to this policy.

Surrogacy arrangements will not be funded, but we will fund treatment (IVF component and storage) in identified (fertile) surrogates, where this is the most suitable treatment for a couple infertility problem and the eligibility criteria are met.

**Note**: Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

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**Date effective from**: 16\(^{th}\) May 2017
**Date published**: FINAL 12th May 2017
**Review date**: April 2018

**Author**: Interim Planned Care Lead North Kirklees & Wakefield CCG

**Clinical Reviewers**: N/A (Taken from existing Policies)

**Approved by**: Clinical Strategy Group (NKCCG) and Clinical Cabinet (WCCG)

**Responsible Officers**: Interim Chief Operating Officer, North Kirklees & Wakefield CCG
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care
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<tr>
<td>PROCEDURE/TREATMENT</td>
<td>10.2.28 – LYCRA GARMENTS OSCAR REF: IFR28 05/2017</td>
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<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>Criteria for Funding: The patient must be on the caseload of the referring clinician.</td>
</tr>
<tr>
<td></td>
<td>• The patient should have cerebral palsy or similar condition with significantly abnormal postural muscle tone.</td>
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<td>• There are no contraindications present (see below).</td>
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<td>• Referral should identify the specific significant benefits offered by the therapy for this patient.</td>
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<td>• Evidence provided that other therapies have been considered but were deemed to be insufficient.</td>
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<td>• Evidence of the patient / carer’s willingness to comply with treatment (e.g. signed agreement or previous successful use).</td>
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<td></td>
<td>• If the patient is over 18, successful previous use of Lycra garments and benefits evidenced.</td>
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<tr>
<td></td>
<td>• Requests for replacement garments should include a user or professional evaluation of benefits to add to the evidence base on this technology.</td>
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<tr>
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<td><strong>Contraindications</strong></td>
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<td>• Lycra garments are contraindicated when adequate monitoring and supervision are not available, there is deemed to be a lack of purposeful intent or, dependent on site of the garment, if severe epilepsy or chronic respiratory problems are present. Lycra splinting is not recommended if there is severe uncontrolled reflux or chronic skin conditions.</td>
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<tr>
<td></td>
<td>• Problems with comfort, reflux sickness and putting on / taking off the suit have been reported. Temperature can also be an issue, particularly in summer. These factors may all impact on compliance and motivation of the patient.</td>
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<td>• A study carried out with the support of Scope and Birmingham Community Health Trust from 1998 – 2000 also found that some people stop wearing the garments altogether because of:</td>
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<td></td>
<td>o The level of support needed to get the garments on and off</td>
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<td></td>
<td>o Toileting issues</td>
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<td></td>
<td>o Garment took too long to dry after washing</td>
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<td></td>
<td>o Unable to maintain the function gains achieved without continued use</td>
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<tr>
<td></td>
<td>• The above considerations should be taken into account before referring for Lycra garments.</td>
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**Note:** Funding for patients meeting the above criteria will be considered on
an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

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# Policy Statement

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<th>Status</th>
<th>Criteria Led Requiring Individual Funding Request</th>
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| **Procedure/Treatment** | 10.2.29 – Functional Electrical Stimulation (FES) - Policy for Foot Drop of Central Neurological Origin  
Oscar Ref: IFR29 05/2017 |

## Eligibility Criteria

The objective for this Commissioning Statement is to:

- **a.** reduce the variation in access to Functional Electrical stimulation (FES).
- **b.** ensure that Functional Electrical stimulation (FES) is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- **c.** promote the cost-effective use of healthcare resources.

This policy is in line with the guidance in NICE IPG 278 - Functional Electrical Stimulation for drop foot of central neurological origin:

http://www.nice.org.uk/Guidance/IPG278

### Criteria

#### Inclusion

The CCGs routinely commission Functional Electrical Stimulation (FES) for drop foot, with the non-implantable device (skin surface FES - OPCS A70.7 application of transcutaneous electrical nerve stimulator), in line with NICE IPG278. Provisions for clinical, governance, consent, audit and research are fully expected to be in place for this service.

- The patient must be over 18 years of age and being treated for foot drop (deficit of dorsiflexion and / or eversion of the ankle) which must be of central neurological origin, due to an upper motor neurone lesion i.e. one that occurs in the brain or spinal cord at or above the level of T12.
- Upper motor neurone lesions resulting in dropped foot occur in conditions such as stroke, brain injury, multiple sclerosis, incomplete spinal cord injury at T12 or above, cerebral palsy, familial /hereditary spastic paraparesis and Parkinson's disease.

#### Exclusion

The following forms of FES are not commissioned by the CCGs:

- Other forms of electrical stimulation for conditions other than foot drop
- FES for upper limb
- Implanted FES
- Wireless FES

The CCGs do not routinely commission the wireless or implantable devices.
Funding will only be considered for wireless or implantable devices where there are exceptional clinical circumstances. The clinician needs to submit an application to the CCG’s Individual Funding Request (IFR) Panel. Clinicians can submit an IFR if they feel there is a good case for exceptionality as described in the Wakefield CCG Policy for IFR.

Where the patient has previously been provided with the treatment with limited or diminishing benefit, the IFR process should be followed.

**Note:** Funding for patients meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

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<tr>
<td>PROCEDURE/TREATMENT</td>
<td>10.2.30 - Spinal Injections (Therapeutic) for Pain Related to the Lumbar Spine OSCAR ref: IFR 30 12/2017</td>
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<td>SPINAL THERAPEUTIC INJECTIONS</td>
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<td>NICE guidance (NG59) clearly states: <em>Do not offer spinal injections for treating low back pain. Pathway Box 9 This refers to:</em></td>
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<tr>
<td></td>
<td>1. Epidural Steroid Injections</td>
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<td>Epidural steroid injections for sciatica and spinal stenosis have an unclear therapeutic effect, but may help reduce pain for a short time in some people.</td>
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<td>2. Facet Joint Injections</td>
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<td>A cervical, thoracic or lumbar facet joint injection involves injecting a small amount of local anaesthetic (numbing agent) and/or steroid medication into one or more facet joints. The therapeutic effect is also unclear but they may help reduce pain for a short time in some people.</td>
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<td>3. Selective Nerve Root Block Injections (SNRB), Primarily used to diagnose the specific source of nerve root pain (such as a facet joint medial branch block) and secondarily, for temporary therapeutic relief of low back pain and/or leg pain, such as during surgical procedures.</td>
</tr>
<tr>
<td>ELIGIBILITY CRITERIA</td>
<td>This policy addresses <em>therapeutic</em> use of spinal injections. It does not address diagnostic indications.</td>
</tr>
<tr>
<td></td>
<td>1) Spinal therapeutic injections in the lumbar spine should not be routinely commissioned for patients with <em>chronic</em> (&gt; 3 months duration) non-specific back pain with or without sciatica.</td>
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<td>2) Spinal therapeutic injections in the lumbar spine should not be routinely commissioned for patients with <em>acute</em> (&lt;3 months duration) episodes of back pain.</td>
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<td><strong>Exceptions:</strong></td>
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<td>Following the Nov 2016 NICE guideline (NG 59) for the management of low back pain and sciatica in the over 16’s, CCGs routinely commission a <strong>single injection only for acute and severe sciatica</strong> of less than &lt;3 months duration, for people who would be considered for surgery.</td>
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<td><strong>Repeat Spinal Injections</strong></td>
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<td>Repeat injections <strong>should not</strong> be routinely provided as there is a lack of high quality supporting evidence for long term benefit and clinical advice suggests</td>
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diminishing returns with increased risk of adverse events.

Repeat injections, up to a **maximum of 2 in total**, may be commissioned only:
Following a specialist multi-disciplinary pain management team assessment which concludes that:
- benefits outweigh harm to the patient;
- there is documented evidence from the patient’s previous medical history of substantial and sustained benefit; for example, if there has been a >50% reduction in symptoms for >12 weeks with documented evidence of **improved health function** in physical activity/role and emotional and social role function.

**Referrals**
On referral to the specialist multidisciplinary pain management service, patients must be informed that the referral is for **assessment and development of a pain management plan by the service with focus on multimodal self-management approach**.

For people where there is clear documented evidence of a pre-existing chronic, persistent or long-term pain (> 3months duration) it should be made clear that the emphasis will be on **supporting their confidence and skills to self-manage** their condition.

Patients should not be under the impression that the decision to provide an injection has already been made or that repeat injections are routinely available.

**Note:** Funding for patients not meeting the above criteria will be considered on an individual basis where their GP or consultant has completed the necessary Individual Funding Request Form. Each individual case will be reviewed via the CCGs Individual Funding Request process. (Appendix 4 – NHS North Kirklees CCG Individual Funding Request Application Form and Appendix 6 NHS Wakefield CCG Individual Funding Request Application Form)

These will be considered by the CCG as follows:
- For selected patients where in exceptional circumstances following participation in a **comprehensive pain self-management programme** designed and delivered according to British Pain Society Guidelines for PMPs for Adults, (2013) it will enable improved health functioning to maximise independence such as return or stay in work, carer functioning.
- Pain self-management is more challenging due to coexisting physical or mental illness or frailty.
- Patients have been reviewed by a **Chronic Pain Management Medicine Specialist as part of a holistic MDT assessment**, who will then be
required to complete the Prior Approval Template if further injections are considered appropriate. A detailed copy of the assessment must be included with the completed template.

In exceptional circumstances where it is considered by the Chronic Pain Management Medicine Specialist as part of a holistic MDT assessment that additional injection therapy is the only option for treatment. There must be a detailed reason for this, such as the evidence of a co-morbid life-limiting condition and a plan and timescale for proposed treatment.

Approval must be obtained BEFORE commencement of any additional injections.

Attached at Appendix 2 is the Prior Approval Funding Request Form

**NOTE: Lifestyle Factors - Best Practice (This is not a restriction to this policy unless otherwise stated)**

NICE guidance (NG59) clearly states that the decision to refer a person for a surgical opinion should not be influenced by their BMI, smoking status or psychological distress. However, the following should be considered:

- **Obesity** - Patients with a BMI >30 should be encouraged by their Clinician to lose weight prior to surgery and signposted to appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards. There is a clinical balance between risk of surgical complications with obesity and the risk to delaying any surgery.

- **Smoking** - In line with ‘Healthy Lives, Healthy People; a tobacco control plan for England’, local authorities and health professionals are committed to encourage more smokers to quit. Smoking remains the leading cause of preventable morbidity and premature death in England. There is sufficient evidence to suggest that people who smoke have a considerably increased risk of intra- and post-operative complications such as chest infections, lung disorders, wound complications and impaired healing.

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<tr>
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<td>DECEMBER 2017</td>
<td>FINAL DECEMBER 2017</td>
<td>April 2018 or when new NICE Guidance is available</td>
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</table>
| Author | Interim Planned Care Lead NHS North Kirklees & NHS Wakefield CCG  
Senior Commissioning Manager NHS Wakefield CCG |
|--------|-----------------------------------------------------------------------------------------------------|
| Clinical Reviewers | (i) GPs: NHS North Kirklees CCG and NHS Wakefield CCG  
(ii) Independent pain management specialists. |
| Approved by | Clinical Strategy Group (NKCCG)  
and  
Clinical Cabinet (WCCG) |
| Responsible Officers | Interim Chief Operating Officer, North Kirklees & Wakefield CCG  
NHS North Kirklees CCG & NHS Wakefield CCGs GP Leads Planned Care |
| Reference: | 1. Low back pain and sciatica in over 16s: assessment and management (Nov 2016)  
   [https://www.nice.org.uk/guidance/NG59](https://www.nice.org.uk/guidance/NG59)  
2. Non-specific low back pain and sciatica: management – NICE  
3. NICE Evidence Search | Spinal injections  
4. NICE Evidence Search | facet joint injections  
5. NICE Evidence Search | lumbar spine injections  
   [https://www.evidence.nhs.uk/search?q=lumbar+spine+injections](https://www.evidence.nhs.uk/search?q=lumbar+spine+injections)  
6. NICE Evidence Search | epidural guidelines  
7. NICE Evidence Search | spinal stenosis treatments  
   [https://www.evidence.nhs.uk/Search?q=spinal+stenosis+treatments](https://www.evidence.nhs.uk/Search?q=spinal+stenosis+treatments)  
8. NICE Evidence Search | epidural steroid injection - NHS Evidence  
9. NICE Evidence Search | epidural steroid injection - NHS Evidence  
   [https://www.evidence.nhs.uk/search?q=epidural+steroid+injection](https://www.evidence.nhs.uk/search?q=epidural+steroid+injection)  
10.3 Exceptional Cases

A patient may be considered exceptional to the CCGs commissioning policy if the following apply:

• The patient is suffering from a medical condition for which the CCGs have commissioning responsibility AND

• The patient’s particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment AND

• There are good grounds to believe the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

The CCGs are committed to ensuring equality of access of services. Therefore, when assessing exceptionality, the CCGs will only consider factors which are relevant to assessing the potential benefits or risks of the request.

Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. Response to an intervention will not be considered to be an exceptional factor.

11 Patient Transport

The CCGs commission transport services in line with the terms and conditions set out in the DH paper Healthcare Travel Costs Scheme – Instruction and guidance for the NHS. Department of Health guidelines state patients are eligible to use patient transport where their medical problems would be made worse if they used another means of transport such as a bus, taxi or their own vehicle to get to hospital or they suffer with severe mobility problems. Eligibility for transport services will be assessed against the criteria by the referring clinician at the time of the request for transport. Escorts are allowed to use patient transport with a patient who is under the age of 16 or with an adult who has been assessed as vulnerable.

12 Continuing Care, Continuing Healthcare and Funded Nursing Care

Continuing Care (CC) is defined as care provided over an extended period of time to a person aged 18 or over, to meet physical or mental health needs that have arisen as a
result of disability, accident or illness. Continuing Healthcare (CHC) means a package of continuing care that is arranged and funded solely by the NHS.

Funded Nursing Care (FNC) is the element of care a person receives in a care home from a qualified nurse which is funded by the NHS at a nationally determined rate.

Eligibility for CC, CHC and FNC is determined by national criteria using processes and tools which are specified in the Department of Health National Framework for NHS Continuing Healthcare and NHS-funded Nursing Care (2012b).

Eligibility is determined by need and not by diagnosis. The CCGs are responsible for determining a patient's eligibility. Assessments may be undertaken by professionals within other organisations and recommendations made, but the final decision rests with the CCGs as the commissioning organisation.

Eligibility will only be considered once an individual has become clinically stable and has reached their full potential. If a patient is in need of further treatment or rehabilitation, then their eligibility for CC, CHC or FNC will not be considered.

All assessments will be made with the full involvement of the individual and / or their representatives.

An individual may also cease to be eligible. This will be determined by a review of their health needs. If a patient is found to no longer be eligible, then the NHS will not continue to fund this care. The patient (and / or their representative) will be given 28 days’ notice that funding will be withdrawn.

Every effort will be made to work with eligible patients to provide a package of care or placement which will meet identified need. Patient preferences will be taken into account. A final decision however, on both the service provider(s) and content of a package or placement lies with the CCGs.

An individual is entitled to ask for a review of a decision made on their eligibility. This will be addressed in accordance with the National Framework and local policy. The CCGs will consider each request individually via the Continuing Care Commissioning team (not through complaints processes). Where it is decided that eligibility will not be reviewed, a full explanation will be provided in writing.

Occasions may arise where a patient is transferred from an acute hospital setting into a care home bed on a temporary basis fully funded by the NHS. Unless an assessment
for CHC eligibility has been undertaken, then the patient should not be considered as a CHC patient.

Arrangements under the following sections below do not relate to Continuing Care, Continuing Healthcare and Funded Nursing Care arrangements:

- Independent Sector Services;
- Retrospective payments to patients who have paid for treatment in the Independent Sector and Services and Interventions with Eligibility Criteria.
- Kirklees also has a CHC Commissioning Policy for CHC

13  New Technologies Including New Drugs

13.1 New Technologies

Without recognised NICE or other national guidance the CCGs will consider commissioning new technologies in instances where all available current treatments have failed or are not suitable. Also where a relevant clinician responsible for the patient’s care puts forward a case through an Individual Funding Request (IFR) with evidence that the new technology should be considered for a patient.

The request must provide evidence that current treatment is not suitable, be fully supported by the clinician and should identify a suitable recognised provider, including reference to evidence that the new technology therapy is effective.

In the case of new or experimental treatment being authorised, good practice would be to encourage involvement in any associated clinical trials or research, where possible, so as to add to the evidence base of the treatment. This supports further research into areas where the evidence base is limited.

A case of this nature will be considered on an individual basis and should be submitted in line with the process outlined in the CCGs ‘Policy for Individual Funding Requests’.

13.2 Horizon Scanning New Medicines

Horizon scanning aims to identify advances in medicine developments that are likely to become available to the NHS as these may have significant implications for clinical practice, or finance.
South West Yorkshire Area Prescribing Committee will undertake necessary horizon scanning on a regular basis on behalf of the CCGs. Horizon scanning will form the basis of policy development for individual treatments.

All commissioning policies relating to new drugs will be authorised by the CCGs Medicines Optimisation Groups and will be made available on the CCGs website.

**13.3 Care of Those in Agreed Clinical Trials**

All clinical trials should have had the appropriate prior approval including ethical approval from the NHS National Research Ethics Service (which is beyond the scope of this policy). However, all clinical trials should contain an ethical exit plan which will need to be designed around the specific needs of participants in the trial. The exit plan should be in place and agreed prior to the trial starting. This will document how the participant’s care will be delivered following the end of the trial and should be carefully explained to the patient prior to starting the trial. This will help the patient to make an informed decision about agreeing to participate in the trial.

In the event that a trial is coming to an end and a clinician wishes to continue the use of a treatment or drug not in a way described in the exit strategy of the research proposal, the clinician must submit a case to the Individual Funding Request panel. This must be done with suitable notice for the case to be heard in full.

**14 Independent Sector Services and Any Qualified Provider Services**

Where pathways and contractual agreements exist between the CCGs and independent sector providers, patients are authorised for treatment by those independent sector providers for the services covered by the agreement.

Where neither a pathway nor contract exists, the CCGs would only consider such a request in instances where all available NHS options have failed or are proven to be unsuitable. The requesting NHS clinician (with an NHS contract) responsible for the patient’s care should put a case together with evidence that the Independent Sector should be considered.

In such an instance, the request must provide evidence that NHS options are not available or are unsuitable. The request must be fully supported by the clinician and should identify a suitable recognised provider. Where necessary it should provide information about the suggested provider’s competence and its safety record. The
request needs to be for an eligible service, intervention or treatment covered by this policy.

A case of this nature will be considered on an individual basis and should be submitted in line with the process for Individual Funding Requests.

15 Retrospective Payments to Patients who have paid for Treatment in the Independent Sector

In some cases, patients enter into private agreements with Independent Sector providers for healthcare without notifying or gaining authorisation from the CCGs. This decision may be made for a number of reasons. At a later date, they may wish this service to be paid for by the NHS and contact the CCGs asking for retrospective funding.

The CCGs do not make retrospective payments for treatments. This decision can be appealed against where all the following exists (but this does not guarantee that the payment will be made):

- An independent NHS clinician supports a patient claim;
- The clinician provides evidence that NHS options were not made available within acceptable timescales;
- That gross inadequacy of NHS services (either treatment or information provided) occurred at the time that the patient made their decision to enter a private agreement with the Independent Sector;
- A clear, evidenced reason why the patient and referring clinician were unable to bring a request to the attention of the CCGs prior to the commencement of treatment; and
- Where the service, intervention or treatment is in accordance with those commissioned through this policy.

If this information is provided, then a case of this nature must be submitted to the CCGs Chief Officer and will be considered on an individual basis.

Please note if there is no clear evidence why an issue of this nature was not brought to the attention of the CCGs prior to the commencement of treatment, and it is perceived that if it had the issue could have been resolved, then the CCGs are unlikely to retrospectively fund such procedures.
16 Reimbursement of Living Donor Expenses

The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 forbid the offer or payment of any inducement for the supply of a human organ. However, it does not prohibit payment of reasonable expenses to a donor for travel and accommodation and any loss of earnings incurred, if directly attributable to his/her donation of an organ.

The purpose of discretionary reimbursement is to ensure that loss of earnings or other financial disincentives does not act as a constraint on individuals wishing to act as a live transplant donor.

Department of Health guidance states the reimbursement of living donor expenses is permitted and should be so if the live transport is permitted under the Human Tissue Act. The NHS is not legally obliged to do so, but as a live donor transplant is an option for some patients (e.g. in liver failure), payment of the cost of the donor operation and any associated donor expenses is justified.

The CCGs will consider reimbursement in line with the NHS England Specialised Services Policy.

17 Overseas Care

The CCGs follow national policy in relation to overseas care. Please note that any changes to national policy will supersede the below.

17.1 European Economic - Travelling

The European Health Insurance Card (EHIC) (replaced E111)

EHIC lets patients get state healthcare at a reduced cost or sometimes for free. It will cover patients for treatment that is needed to allow them to continue their stay until their planned return. It also covers them for treatment of pre-existing medical conditions and for routine maternity care, as long as they're not going abroad to give birth.

The EHIC is valid in all European Economic Area (EEA) countries, including Switzerland.
For more information about what is covered in each country see our country-by-country guide.

17.2 European Economic – Planned Treatment

Department of Health Guidance, Cross Border Healthcare and Patient Mobility states that if a patient is eligible for NHS funded healthcare but plans to be treated in an EEA country, there are two ways to access NHS funding:

**The S2 Route (Formerly E112)**

This is a direct arrangement between the NHS and the state healthcare provider in the country of your choice. Prior approval is required.

The S2 (formerly E112) route entitles the patient to state-funded treatment in another European Economic Area (EEA) country or Switzerland. Treatment will be provided under the same conditions of care and payment as for residents of that country. This could mean the patient has to pay a percentage of the costs, however, the patient may be able to claim back some or all of the co-payment when they return to the UK.

In some countries, as in the UK, care is completely free. This means the S2 will cover 100% of the cost of care, so the patient would not be required to pay any treatment costs upfront.

The NHS would pay the treating country's contribution and the patient would be expected to pay the ‘co-payment charge’. Reimbursement of this charge may be sought upon returning to the UK.

**The EU Directive on Cross-Border Healthcare (or Article 56)**

Generally, the patient will have to pay the costs of treatment abroad and then claim reimbursement from the NHS when they return. Depending on the treatment, it may be necessary to obtain authorisation from NHS England before receiving treatment. Types of services requiring prior authorisation are detailed on the following link:

The EU Directive on cross-border healthcare (or Article 56) may allow a patient to obtain reimbursement of the costs of their procedure in an EEA country after paying the total cost of treatment up front.

Unlike using the S2, patients could receive this contribution to either private or state provided treatment. The treatment must be one that is available through the NHS. Reimbursement can only be issued up to the cost of being treated locally under the NHS; there is no guarantee that a patient will receive funding.

For more information contact NHS England (email nhscb.europeanhealthcare@nhs.net) before arrangements are made abroad.

### 17.3 Countries Outside of the EEA

If the patient wants to be treated outside the EEA (European Economic Area), the condition must be of a serious nature and the treatment requested must be established (not experimental), not available in the UK or the EU, and it must be likely to be of significant benefit to the patient’s health. If it fulfills these criteria, the CCGs will consider the request, but are not under any obligation to do so or to approve the application.

A case of this nature will be considered on an individual basis and should be submitted in line with the process outlined in the Individual Funding Request policy. Clinicians will need to demonstrate how best their patient meets the above criteria as part of the individual funding request.

### 18 Commissioning of Services for Overseas Visitors and Asylum seekers

#### 18.1 Charges to Overseas Visitors

Guidance on charges for NHS treatment and exemptions for people visiting the UK is given in the following legislation; ‘The National Health Service (Charges to Overseas Visitors) Regulations 2011.’ and the Guidance On Implementing the Overseas Visitors Hospital Charging Regulations. Is still the most up to date?

NHS trusts have a legal obligation to identify and charge those people not entitled to free NHS hospital treatment under this legislation. NHS Trusts will make their decision in accordance with the legislation.

No charge may be made or recovered in respect of any relevant services provided to an overseas visitor which fall within the following:
a) Accident and emergency services, whether provided at a hospital accident and emergency department, a minor injuries unit, a walk-in centre or elsewhere, but not including any services provided -
   (i) After the overseas visitor has been accepted as an in-patient; or
   (ii) At an outpatient appointment;

b) Services otherwise than at, or by staff employed to work at, or under the direction of, a hospital;

c) Family planning services;

d) Treatment in respect of a disease listed in Schedule 1 of the above guidance;

e) Treatment for sexually transmitted infections, but in the case of services which relate to infection with Human Immunodeficiency Virus, only to the extent that they consist of a diagnostic test for evidence of infection with the Virus and counseling associated with that test or its result;

f) Services provided to an overseas visitor who is liable to be detained in a hospital or, received into guardianship under the Mental Health Act 1983(7) ‘(the 1983 Act)’ or any other enactment authorising detention in a hospital by reason of mental disorder, or subject to a community treatment order under the 1983 Act(8);

g) Treatment which is provided in circumstances where-
   (i) A requirement to submit to the form of treatment concerned is imposed by, or included in, an order of a court; and
   (ii) Paragraph (f) does not apply.

Further exceptions apply to the provision of NHS treatment to those that are not ordinarily resident in the UK as governed by the NHS (Charges to Overseas Visitors), Regulations 2011. Full details are available in the legislation but some specific areas are given below.

18.2 Failed Asylum Seekers

The CCGs position on the entitlement of failed asylum seekers is in line with national guidelines ‘The NHS (Charges to Overseas Visitors) Regulations 2011’, as follows:

- Failed asylum seekers who have commenced a course of treatment without charge are to complete that course without charge (what constitutes a ‘course of treatment’ is a clinical decision);
- Treatment in A&E remains free of charge;
• Treatment which is immediately necessary, including all maternity treatment, must not be withheld, but Trusts are still obliged to seek recovery of their charges even when there is no prospect of payment being made;
• The obligation to charge for urgent and non urgent treatment remains, but a Trust can exercise its discretion to choose to treat individuals who cannot or will not pay. Trusts can seek a deposit of the likely charge of the treatment required before the treatment is delivered.

18.3 Overseas Visitors Exempt from Charges, Including Refugees, Asylum Seekers and Children in Care

No charge may be made or recovered in respect of any relevant services provided to an overseas visitor who:

a) Has been granted temporary protection, asylum or humanitarian protection under the immigration rules made under section 3(2) (general provisions for regulation and control) of the Immigration Act 1971(12);

b) Has made an application, which has not yet been determined, to be granted temporary protection, asylum or humanitarian protection under those rules;

c) Is currently supported under section 4 or 95 of the Immigration and Asylum Act 1999(13); or

d) Is a child, taken into local authority care under the Children Act 1989(14).

19 Translation Services

NHS England commission translation services (including sign language) for patients to access primary care services. The CCGs expect providers to make their services accessible to all those requiring translation services.

20. Equality Impact Assessment

All public bodies have a statutory duty under the Race Relation (amendment) Act 2000 to “set out arrangements to assess and consult on how their policies and functions impact on race equality.” This obligation has been increased to include equality and human rights with regards to disability, age and gender. The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

In order to meet these requirements, a single equality impact assessment is used to assess all its policies/guidelines and practices.

This policy guidance was found to be compliant with this philosophy after applying
The Equality Impact Assessment Checklist Tool (Appendix 8).

21 References

Department of Health (2013). The NHS Constitution the NHS belongs to us all. Available at:-


Health and Social Act (2012). Available at: -


Lock, D 2011, What does the duty on PCT’s to give reasons for an individual treatment decision mean in practice; Barrister and Head of Public Law at No5 Chambers North Yorkshire and York PCT, High Cost Healthcare Commissioning Policy. November 2007


The National Health Service Bill (2006)


22 Referenced webpage links

NHS England Manual for Prescribed Specialised Services

NHS England Clinical Policies and Statements for Specialised Services Commissioning
http://www.england.nhs.uk/policies/

Department of Health ‘Healthcare Travel Costs Scheme – Instructions and guidance for the NHS

National Framework for NHS Continuing Healthcare and NHS Funded Nursing Care

Reimbursement of Liver Donor Expenses Policy
https://www.england.nhs.uk/?s=living+donor+expenses

Country by country guide
http://www.nhs.uk/NHSEngland/Healthcareabroad/countryguide/Pages/EEAcountries.aspx
EU Directive on cross-border healthcare (or Article 56) on Services requiring prior authorisation

For more information and to ensure you don’t have any difficulties when claiming back your money, contact NHS England before making any arrangements abroad.
nhscb.europeanhealthcare@nhs.net

NHS Charges to Overseas Visitors Regulations 2011

Guidance on eligibility for free hospital treatment under the NHS
Appendix 1

Commissioning Responsibilities of CCGs and NHS England

The below tables explain the commissioning responsibilities CCGs, including the CCGs, and the complimentary services commissioned by NHS England, local authorities and Public Health England. As integration of services is essential this explains how services commissioned by the different commissioning organisations will relate to each other.

Services to be commissioned by CCGs

<table>
<thead>
<tr>
<th>CCG commissioning</th>
<th>Related NHS CB commissioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent and emergency care (including 111, A&amp;E and ambulance services) for anyone</td>
<td>Urgent care provided under GP contracts</td>
</tr>
<tr>
<td>present in your geographic area</td>
<td>Urgent dental care</td>
</tr>
<tr>
<td>Out-of-hours primary medical services (for everyone present in your area), except</td>
<td>Specialised and highly specialised services</td>
</tr>
<tr>
<td>where this responsibility has been retained by practices under the GP contract</td>
<td>Hospital and community dental services</td>
</tr>
<tr>
<td>Elective hospital care</td>
<td>Public health services for children from pregnancy to aged 5</td>
</tr>
<tr>
<td>Community health services (such as rehabilitation services, speech and language</td>
<td>(Healthy Child Programme 0-5) including health visiting and</td>
</tr>
<tr>
<td>therapy, continence services, wheelchair services, and home oxygen services, but</td>
<td>family nursing partnership (commissioned on behalf of Secretary</td>
</tr>
<tr>
<td>not public health services such as health visiting and family nursing)</td>
<td>of State)</td>
</tr>
<tr>
<td>Other community-based services, including (where appropriate) services provided by</td>
<td>Antenatal and newborn screening aspects of maternity services</td>
</tr>
<tr>
<td>GP practices that go beyond the scope of the GP contract</td>
<td>Health services (excluding emergency care) and public health</td>
</tr>
<tr>
<td>Rehabilitation services</td>
<td>services for people in prisons and other custodial settings</td>
</tr>
<tr>
<td>Maternity and newborn services (excluding neonatal intensive care)</td>
<td>Health services (excluding emergency care services) for members</td>
</tr>
<tr>
<td>Children’s healthcare services (mental and physical health)</td>
<td>of the armed forces and their families (those registered with</td>
</tr>
<tr>
<td>Services for people with learning disabilities</td>
<td>DMS)</td>
</tr>
</tbody>
</table>
| Mental health services (including psychological therapies) | Mental health interventions provided under GP contract
Some specialised mental health services
Secure psychiatric services |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS continuing healthcare</td>
<td>Operation of Independent Review Panels</td>
</tr>
<tr>
<td>Infertility services</td>
<td>Infertility services for the armed forces and some infertility services for veterans in receipt of compensation under the Armed Forces Compensation Scheme on grounds of infertility</td>
</tr>
</tbody>
</table>

### Services to be commissioned by NHS England

<table>
<thead>
<tr>
<th>NHS England commissioning</th>
<th>Related CCG commissioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential and additional primary medical services through GP contract and nationally commissioned enhanced services</td>
<td>Out-of-hours primary medical services (where practices have opted out of providing OOH services under the GP contract)</td>
</tr>
<tr>
<td>Out-of-hours primary medical services (where practices have retained the responsibility for providing OOH services)</td>
<td>Community-based services that go beyond scope of GP contract (akin to current Local Enhanced Services)2</td>
</tr>
<tr>
<td>Pharmaceutical services provided by community pharmacy services, dispensing doctors and appliance contractors</td>
<td>Meeting the costs of prescriptions written by member practices (but not the associated dispensing costs)</td>
</tr>
<tr>
<td>Primary ophthalmic services, NHS sight tests and optical vouchers</td>
<td>Any other community-based eye care services and secondary ophthalmic services</td>
</tr>
</tbody>
</table>
| All dental services, including primary, community and hospital services and including urgent and emergency dental care | Emergency care, including 111, A&E and ambulance services, for prisoners and detainees present in your geographic area
Health services for adults and young offenders serving community sentences and those on probation
Health services for initial accommodation |
<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health services for members of the armed forces and their families</td>
<td>Health services for veterans or reservists (when not mobilised), for whom normal commissioning responsibilities apply.</td>
</tr>
<tr>
<td>(those registered with DMS)</td>
<td>Emergency care, including A&amp;E and ambulance services, for serving armed forces &amp; families registered with DMS practices present in your geographic area.</td>
</tr>
<tr>
<td>Prosthetics services for veterans</td>
<td></td>
</tr>
<tr>
<td>(Primary care for members of the armed forces will be commissioned by</td>
<td></td>
</tr>
<tr>
<td>the Ministry of Defence)</td>
<td></td>
</tr>
<tr>
<td>Specialised and highly specialised services</td>
<td>Related services along patient pathways.</td>
</tr>
</tbody>
</table>

**Public health services to be commissioned by NHS England**

- Public health services for children from pregnancy to age 5 (Healthy Child Programme 0-5), including health visiting, family nurse partnership, responsibility for Child Health Information Systems
- (Responsibility for children’s public health 0-5 due to transfer to local authorities in 2015)
- Immunisation programmes
- National screening programmes
- Public health care for people in prison and other places of detention
- Sexual assault referral services


Accessed June 2015
Appendix 2 – Prior Approval Funding Request Form

NHS North Kirklees and NHS Wakefield Clinical Commissioning Groups

Prior Approval Funding Requests Referral Form

This form should be completed by the clinician with the most knowledge of the intervention / procedure that is being requested and the most knowledge of the patient that it is being requested for.

<table>
<thead>
<tr>
<th>Patient’s:</th>
<th>DOB:</th>
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<tbody>
<tr>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>NHS no:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**DETAILS OF REQUEST AND SUPPORTING INFORMATION**

Please ensure that all relevant information is included in this form or is attached to ensure that requests are processed in a timely manner.

**Request for:**


**Clinical information:**

(Please include patient’s current BMI, if relevant to request)
| Options tried: |  |
| Evidence base to support request: |  |
| What clinical outcomes are requested? |  |
| Costs (if known): |  |
| Provider (if known): |  |
I confirm that I have discussed this referral with the patient and they have given consent to share their information with the IFR Team at Greater Huddersfield CCG.

Signed:

Please print name:

Position & address of referring clinician (Practice stamp) & GP Practice if different:

<table>
<thead>
<tr>
<th>Details of where to send this form (Please mark as CONFIDENTIAL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Funding Requests Team</td>
</tr>
<tr>
<td>Greater Huddersfield Clinical Commissioning Group</td>
</tr>
<tr>
<td>Broad Lea House, Bradley Business Park, Dyson Wood Way, Bradley, Huddersfield, HD2 1GZ</td>
</tr>
<tr>
<td>Telephone: 01484 464438</td>
</tr>
<tr>
<td>Safe Haven email: <a href="mailto:GHCCG.IFR-CKW@nhs.net">GHCCG.IFR-CKW@nhs.net</a></td>
</tr>
<tr>
<td>Safe Haven fax: 01484 464062</td>
</tr>
</tbody>
</table>
Appendix 3 - NHS North Kirklees CCG IFR Process

Procedures
An Individual Funding Request (IFR) is a request to a CCG to fund healthcare for an individual who falls outside the range of services and treatments that the CCG has agreed to commission (NHS Confederation 2008b). The process should be both thorough and comprehensive taking into account the legal issues and commissioning principles outlined in the policy above. The process of decision making in all cases should therefore be:

- Consistent – in line with agreed policy
- Concise – often requests for funding are related to care which is required relatively urgently, but not so concise that key issues are marginalised
- Transparent and explicable
- Defensible – based on sound evidence from national or legal guidance

The Individual Funding Request Procedure
The Individual Funding Request procedure can only be initiated by a clinician i.e. the General Practitioner, Consultant or Dentist making a request for funding for a treatment to the CCG. It is the responsibility of the individual seeking funding in conjunction with the referring clinician to ensure that all relevant information is forwarded to the CCG. This should include:

1. An outline of the patient’s problem and the circumstances of the case, including any previous treatment
2. A clear statement of the referral/treatment plan proposed
3. Consideration of whether the patient’s needs could be met within existing Pathways
4. If the care could be provided within existing pathways, a statement of why an alternative referral, which would not be offered to others with a similar clinical need, is a priority in this case
5. If the case is not routinely funded by the CCG through existing care pathways, evidence to show why this patient is exceptional

A referral form (Appendix 4) should be completed by the referring clinician in all cases in order to ensure all the above information is received. The only exception to this is when an alternative proforma is available from individual Trusts requesting high cost drugs for individual patients.

If a referral form is not completed the referral will not be considered until the CCG has received the information that they require to enable a decision to be made.
All requests for funding should be referred in writing, preferably typed, in the first instance to the IFR Team. All requests must be legible in order to avoid delays in consideration of the request. On receiving a request, the IFR Team will:

- Enter the request onto a secure database
- Assign a unique Individual Funding Request (IFR) number
- Create a file within which to keep all correspondence and information relating to the request
- Log all correspondence onto the secure database

The IFR Team should collate the information supplied for each case and ensure it is passed on to the screening panel to enable them to consider each case and complete the screening matrix as comprehensively as possible.

The role of the IFR Team is an administrative role tasked with coordinating the IFR process.

Any queries relating to a specific case at any stage of the process should be communicated by the IFR Team in writing via the GP or referring clinician.

This will enable accurate records of each case to be maintained and enquires to be answered by the most appropriate person.

The IFR Team can be contacted either by the patient or referring clinician if clarification is required regarding the IFR process.

There will be three stages for considering IFR requests;

```
Stage One – Screening process
Screening Panel
  ↓
Exceptional Cases Committee
  ↓
Appeals Committee
```

Stage One – Screening process
Screening cases is recommended as good practice by the NHS Confederation (2008b). The role of screening is to review all applications in relation to current national, regional or local guidance and/or policies as well as identifying any previous precedents that have been set.
The screening process will operate within principles set out in the policy document.

**Outcomes from the Screening Process Recommendations for Approval**

Individual Funding Requests can be recommended for approval to the Exceptional Cases Committee as part of the screening process, if the referring clinician is requesting approval for treatment on the restricted treatments list where the patient already meets agreed criteria. Requests can also be recommended for approval if the request clearly meets the criteria specified for that indication in NICE guidance. The patient and referring clinician will be informed in writing within 5-10 working days of the Screening Panel meeting.

Requests for high cost drugs can be recommended for approval by the Screening Panel if the request is supported by local, regional or national policy or guidance. The Screening Panel will also refer a request to the ECC for high cost drugs or rare conditions where there is no clear guidance or criteria available to enable them to make a recommendation. To aid the decision-making process, the Screening Panel may request an evidence review to be carried out by the Public Health Team as per the memorandum of understanding dated April 2014.

The Chair of the Exceptional Cases Committee will take responsibility for signing off approved requests.

It should be noted that in severe financial difficulties the following has occurred in 2006 by Huddersfield PCT’s and thereafter by Kirklees PCT until early 2007:

- Moratorium: In circumstances of severe financial constraint, consideration of Individual Funding Requests can be suspended by the CCGs. It is lawful and fair to restrict treatments on the basis of costs in extreme circumstances. However it will still be necessary to screen requests and continue to support those that the ECC agree meet the following criteria:
  - The condition is immediately life threatening
  - That undue delay would result in a real and imminent risk of harm, e.g. death, infirmity or handicap
  - That the procedure needs to be carried out within a strict time frame as delay would result in it becoming ineffective

**Refused**

Individual Funding Requests can be refused as part of the IFR process if:

- The individual does not meet agreed criteria
- There is no clear evidence supporting the treatment
• Where the request does not clearly demonstrate exceptionality

In the event of refusal to fund a request, the referring clinician will be advised of the reason for refusal and of the relevant appeals process to follow.

Individual Funding Requests in the following circumstances will normally be refused:
• Where the patient does not take up treatment within one year of approval being granted, then the case will be closed and a new application for funding must be made
• Where an IFR is made by a non-NHS clinician based in a private provider with whom the CCGs do not hold a contract
• Where an IFR is made for treatment within a non-contracted private provider, when equivalent NHS commissioned services are available

Urgent or Emergency Cases
It is recognised that there may be occasions when the Screening Panel receive cases for consideration that need a decision urgently. Given that there would be difficulties in convening the Exceptional Cases Committee at short notice in cases of extreme emergency (for example, someone’s life is dependent on a decision being made) the Screening Panel will pass on its recommendations to the Chief Officer of the CCG or the Head of Strategic Planning & Service Transformation. The Clinical Lead or nominated deputy will also be involved in the decision-making process of urgent or emergency requests.

The decision will be documented and reported to the Exceptional Cases Committee at the next meeting.

While the CCGs will endeavour to respond to such urgent requests as quickly as possible, this should not compromise the quality and validity of the decision making process.

At all times the provider is able to fund a health care intervention pending a decision from the CCGs and the CCGs accept no responsibility for the clinical consequences of any delay in responding to the request.

Both the patient and the referring clinician will be notified of the decision to refer the case to the Exceptional Cases Committee, within 5-10 working days of the Screening Panel. For drugs requests, only the referring clinician or the relevant Trust will be notified in writing of the decision to refer the case to the Exceptional Cases Committee.
All Panels will include agreed representatives for or on behalf of each CCG, as per the compact agreement.

Membership of the Screening Panel
- Head of Service (GHCCG) (Chair)
- Individual Funding Requests Support Officer
- Senior Medicines Commissioning Pharmacist

This is the core membership of the Screening Panel and if for any reason a member of the Panel cannot attend then an agreed deputy will attend the meeting. The Panel will meet on a weekly basis.

Other officers from either CCG or the Public Health Team can be invited to attend the Panel as necessary.

Stage Two – Exceptional Cases Committee
In making a decision the Committee will consider all available clinical history and examine the evidence base where necessary. The Committee will:
- Review each patient request on an individual basis
- Take into account relevant factors which are unique to the patient, e.g. current health status and existing co-morbidities
- Consider if the treatment is necessary and appropriate in relation to individual clinical need, with expected benefits outweighing any risks, and whether there are any exceptional needs or circumstances
- Consider the evidence base for safety and efficacy and if the request is drug related, its licensed indication
- Consider if the treatment is clinically and cost effective with equity of access and provision across the CCG, utilising clinical information (provided by patient’s GP, Consultant or other appropriate clinical staff) and evidence base (regarding clinical and cost effectiveness of the intervention).
- Consider consistent with agreed guidance whether CCG, regional or national that may be available
- Consider other alternative options available for the patient including whether the request can be met by local or alternative providers or whether they are inappropriate for that individual
- Consider if this establishes a precedent or whether there is an existing precedent

The Panel will use the following information to make the decision as to whether the case referred is an exception:
- Information provided by the patient’s GP/referring clinician
- Clinical effectiveness reviews of the intervention requested
• Evidence that all alternative clinical strategies have been exhausted, e.g. conservative and primary care management of the patient’s condition

Applications for Consideration via the Exceptional Cases Process.
In instances where the request is to proceed to the Exceptional Case Committee, the IFR Team will:
• Write to the referring clinician and the patient within 5-10 working days confirming that the request will be considered by the Exceptional Cases Committee. Additional information may be requested at this time. This letter will also inform them of the date of the next Exceptional Cases Committee.
• Write to other health professionals with clinical involvement in the patient’s care for clarification of the patient’s needs, if required and/or appropriate

Decision for Approval or Non-Approval
Whether the request for funding is approved or not, the patient, the referring clinician and the patients GP (where they are not the referring clinician) will be informed in writing of the decision within 5-10 working days of the Exceptional Cases Committee meeting.
Where the request was refused, the Committee will set out their decision and the reasons for it to the referring clinician and GP. The patient will be informed of the decision and encouraged to see their GP to discuss the reasons behind the decision. If the patient does not accept the outcome they can appeal VIA THE REFERRING CLINICIAN ONLY to the Appeals Committee.

Membership of the Exceptional Cases Committee
Membership of the Exceptional Cases Committee is detailed below. It is the expectation that all of these people or their deputies will attend every Committee meeting.
- Chief Officer GHCCG (Chair) or nominated deputy
- Chief Financial Officer NKCCG or nominated deputy
- Lay member (GHCCG or NKCCG)
- A maximum of 4 Clinical Leads (GHCCG and NKCCG)

Each of the above nominated Committee members will have a deputy.
The Committee is quorate with the presence of the following:
- Chief Officer GHCCG (Chair) or nominated deputy
- Chief Financial Officer NKCCG or nominated deputy
- Lay member (GHCCG or NKCCG)
- 2 Clinical Leads (GHCCG and NKCCG)
The Committee will be chaired by the Chief Officer of GHCCG or their Deputy. The Chair will be responsible for checking that the decisions made are accurately recorded and for signing any letters sent to patients and clinicians reflecting those decisions. In case of disagreement, the Chair has the casting vote if necessary.

**Stage three - Appeals Process**

Individuals wishing to appeal against a decision made by the Exceptional Cases Committee must notify the CCG of their intention in writing, via the IFR Team, within 40 working days of the date of the initial decision via their GP or initial referring clinician.

The GP or referring clinician must demonstrate on what grounds they wish to appeal against the decision. An appeal can be made on the following grounds:

- Procedural irregularities (e.g. due process has not been followed or that a Committee has not been quorate to make a decision) or all of the information has not been considered, or new / additional information is to be considered
- The clinician / patient is not happy with the outcome decision. In this case, the appeal will be treated as a formal complaint and the relevant procedure will be implemented

The Individual Funding Requests Team will send a letter reminding patients and clinicians of the approaching deadline for appeal at the midpoint of 20 working days post the Exceptional Cases Committee meeting. If the clinician does not lodge an appeal within the allocated timescales the case will be closed and any further correspondence would start the process again.

**Decision Making Process**

The Appeals Committee considers and decides on appeal applications which challenge due process by reference to this policy.

The duties of the Appeals Committee are set out below:

- To consider and review the Exceptional Cases Committee’s decision in relation to the funding of an individual’s treatment by reference to fair and appropriate application of the process.
- To receive and review all documentation considered by the Exceptional Cases Committee and further submissions received from parties.
- To make a decision to uphold the original decision of the Exceptional Cases Committee or refer the case back to the Exceptional Cases Committee for reconsideration, if there is evidence that all of the relevant information was not considered or that due process has not been followed. In this instance, this will be supported by a written recommendation from the Appeals Committee.
A failure in the process of handling an Individual Funding Request does not necessarily mean that the decision that was made was incorrect (Guidelines from the NHS Confederation 2008b).

**Decision for Approval or Non-Approval**
The Individual Funding Requests Team will write to the patient, referring clinician and GP (where this is not the referring clinician) within 5-10 working days with the Committee’s decision and their reasons. Patients who remain dissatisfied with the Appeal Committee decision will be given the information on potential courses of action as part of the letter detailing the Appeals Committee decision.

**Membership of the Appeals Committee**
It is the expectation that all of these people or their deputies will attend every Appeals Committee meeting. The Appeals Committee is quorate with the presence of the following:
- Clinical Lead
- Senior Manager (GHCCG)
- Senior Manager (NKCCG)
- Lay Member (GHCCG or NKCCG)
- Other representatives, for example from Public Health, can also be invited to be part of the Appeals Committee as required.

The chair of the Appeals Committee will be one of the Senior Managers detailed above.

The IFR Team will co-ordinate the meeting, circulate papers and minute and record the actions / recommendations from the meeting.

**Precedence**
At any point in the decision-making process of the Exceptional Cases Committee or the Appeals Committee a precedent could be set. This means that any decision made can be used to inform future decisions for similar requests. If previous decisions are not taken into account this could form the basis for legally challenging the CCG and the decision made on an Individual Funding Request. Given the significance of setting precedence and its potential impact on future decisions all decisions will be recorded on a secure database by the IFR Team. However, a decision to allow or refuse funding will not be absolutely binding on the CCG but where the CCG departs from a previous decision, clear evidence must be available to justify and support this departure (examples of this might include a patient presenting with slightly different symptoms, or
someone who due to age/weight/ sex/other medication might not respond to treatment in the same way).

Where Individual Funding Requests are to be referred to the Exceptional Cases Committee the Screening Panel will review all previous decisions for the same treatment and indication.

Any relevant decisions made about previous cases that could have an impact on the decision making process for an individual case will be made available to the Committee.

An IFR should not be seen as a mechanism to introduce a new treatment. The request should be seen as genuinely individual. The requesting clinician should also demonstrate that the request is an individual request to fund a treatment, and not about introducing a treatment to a group – however small.

**Treatment outside the European Economic Area (EEA)**
Requests for treatment outside the EEA will be considered in line with the Department of Health Guidelines.
Appendix 4 – NHS North Kirklees CCG Individual Funding Requests
Referral Form

NHS North Kirklees Clinical Commissioning Group

Individual Funding Requests
Referral Form

From 1st February 2017 for treatments and procedures that are subject to the IFR Moratorium, please consider the additional criteria shown below prior to submitting this form. Please evidence within the referral which of the following criteria is applicable;

(i) That the condition is immediately life-threatening or
(ii) That undue delay would result in a real and imminent risk of harm, eg. death, infirmity or other serious consequences or
(iii) That the procedure needs to be performed within a strict time-frame as delay would result in it becoming ineffective.

Treatments and procedures that are subject to the IFR Moratorium

Abdominoplasty / Apronectomy
Allergy Treatments at Independent Sector Providers
Blepharoplasty
Body Contouring Procedures (buttock lift, thigh lift, arm lift etc)
Botulinum Toxin Type A
Breast Asymmetry
Breast Augmentation
Breast Enlargement (revisional surgery)
Breast Reduction (female)
Breast Reduction (male – gynaecomastia)
Circumcision (for religious reasons)
Correction of Hair Loss / Hair Transplantation
Correction of Inverted Nipples
Correction of Male Pattern Baldness
Facial Procedures (face lift, brow lift etc)
Hair Depilation
Hip Arthroscopy
Liposuction
Mastopexy
Osseo-integrated Implants
Pinnaplasty
Repair of External Ear Lobes
Reversal of Sterilisation
Rhinophyma
Rhinoplasty
Sacral Nerve Stimulation (urinary retention and constipation)
Skin and Subcutaneous Lesions (including vascular and benign lesions)
Skin Hypo-Pigmentation
Skin Resurfacing Techniques
Surrogacy
Tattoo Removal

*Note – All of the above procedures will be subject to a criteria review during the period of the Moratorium*

This form should be completed by the clinician with the most knowledge of the intervention / procedure that is being requested and the most knowledge of the patient that it is being requested for.

<table>
<thead>
<tr>
<th>Patient’s Name:</th>
<th>DOB:</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<th>NHS no:</th>
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<table>
<thead>
<tr>
<th>Patient’s Address (include postcode):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**DETAILS OF REQUEST AND SUPPORTING INFORMATION**

Please ensure that all relevant information is included in this form or is attached to ensure that requests are processed in a timely manner

<table>
<thead>
<tr>
<th>Request for:</th>
</tr>
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<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Please include patient’s current BMI, if relevant to request)</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Options tried:</td>
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<td></td>
</tr>
<tr>
<td>Evidence base to support request:</td>
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<td></td>
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<tr>
<td>What clinical outcomes are requested?</td>
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<td></td>
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<tr>
<td>Costs (if known):</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Provider (if known):</td>
</tr>
</tbody>
</table>
Please ensure that Appendix A – Equality Monitoring Form is completed by the patient and is attached to this funding request prior to submission.

I confirm that I have discussed this referral with the patient and they have given consent to share their information with the IFR Team at Greater Huddersfield CCG.

Signed:

Please print name:

Position & address of referring clinician (Practice stamp) & GP Practice if different:

---

Details of where to send this form (Please mark as CONFIDENTIAL)

Individual Funding Requests Team
Greater Huddersfield Clinical Commissioning Group
Broad Lea House, Bradley Business Park, Dyson Wood Way, Bradley, Huddersfield, HD2 1GZ

Telephone: 01484 464438
Safe Haven email: GHCCG.IFR-CKW@nhs.net
Safe Haven fax: 01484 464062

---

Appendix A – Equality Monitoring Form – Patient

To make sure we provide the right services and treat everyone fairly, it is important we collect the following information. Data will be protected and stored securely in line with data protection rules. This information will be kept confidential. We would like you to answer all the questions but it is not required.

The answers to these questions will not affect the decision of the Individual Funding Request that is being submitted by your clinician.

1. What sex are you?
   - [ ] Male
   - [ ] Female
   - [ ] Prefer not to say

2. Which country were you born in?

Black or Black British:
   - [ ] Caribbean
   - [ ] African
   - [ ] Other Black background (please specify in the box below)
3. Do you belong to any religion?
- [ ] Buddhism
- [ ] Christianity
- [ ] Hinduism
- [ ] Islam
- [ ] Judaism
- [ ] Sikhism
- [ ] No religion
- [ ] Other (please specify in the box below)

4. What is your ethnic group?
**Asian or Asian British:**
- [ ] Indian
- [ ] Pakistani
- [ ] Bangladeshi
- [ ] Chinese
- [ ] Other Asian background (please specify in the box below)

**Mixed or multiple ethnic groups:**
- [ ] White and Black Caribbean
- [ ] White and Black African
- [ ] White and Asian
- [ ] Other Mixed background (please specify in the box below)

**White:**
- [ ] English/Welsh/Scottish/Northern Irish/British
- [ ] Irish
- [ ] Gypsy or Irish Traveller
- [ ] Other White background (please specify in the box below)

**Other ethnic groups:**
- [ ] Arab
- [ ] Any other ethnic group (please specify in the box below)

- [ ] Prefer not to say

Please turn over the page
5. Do you consider yourself to be disabled?

☐ Yes  ☐ No
☐ Prefer not to say

Type of impairment:
Please tick all that apply

☐ Physical or mobility impairment
(such as using a wheelchair to get around and / or difficulty using their arms)

☐ Sensory impairment
(such as being blind / having a serious visual impairment or being deaf / having a serious hearing impairment)

☐ Mental health condition
(such as depression or schizophrenia)

☐ Learning disability
(such as Downs syndrome or dyslexia) or cognitive impairment (such as autism or head-injury)

☐ Long term condition
(such as cancer, HIV, diabetes, chronic heart disease, or epilepsy)

☐ Prefer not to say

6. Are you a carer?

Do you look after, or give any help or support to a family member, friend or neighbour because of a long term physical disability, mental ill-health or problems related to age?

☐ Yes  ☐ No
☐ Prefer not to say

7. Are you pregnant?

☐ Yes  ☐ No
☐ Prefer not to say

8. Have you given birth in the last 6 months?

☐ Yes  ☐ No
☐ Prefer not to say

9. Please select the option that best represents your sexual orientation?

☐ Bisexual (both sexes)
☐ Gay (same sex)
☐ Heterosexual/straight (opposite sex)
☐ Lesbian (same sex)
☐ Other
☐ Prefer not to say

10. Are you transgender?

Is your gender identity different to the gender you were assigned at birth?

☐ Yes  ☐ No
☐ Prefer not to say

Thank you for completing this form
Appendix 5 - NHS Wakefield CCG IFR Process

NHS Wakefield CCG will make its general policies available at www.wakefieldccg.nhs.uk

Individual funding requests
An individual funding request (IFR) is appropriate where either of the following applies:

- the CCG has a general policy not to fund a health care intervention for the specified indication but a clinician considers his/her patient to be ‘exceptional’ to that policy, or
- the CCG has no policy in place for the requested health care intervention and indication and the clinical circumstance is so rare that it is unlikely that any other patients will require the intervention.

In responding to an IFR, the CCG accepts no clinical responsibility for the health care intervention or its use or for the consequences of not using the intervention.

Decisions about which health care interventions are to be requested are the responsibility of the treating clinician and the provider organisation. In instances where there is disagreement between clinicians or between the patient and their clinician as to which intervention is to be requested or the manner in which it is to be administered, the CCG will take no part in these discussions other than to provide current commissioning policies. It is the duty of the referring provider organisation to obtain appropriate arbitration in instances of disagreement between clinicians or between patients and clinicians.

What is ‘exceptional’?

Exceptionality should be considered in the context of the CCG general policy for a health care intervention and specified indication.

In general, the CCG must justify the grounds upon which it chooses to fund a health care intervention for a patient when that intervention is unavailable to others with the condition.

A patient may be considered 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 health care intervention AND

• There are good grounds to believe the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

When considering IFRs, the CCG will use the same ethical framework and guidelines for decision making that underpin its general policies for health care interventions. Where social, demographic or employment circumstances are not considered relevant to population based decisions, these factors will not be considered for IFRs.

Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. However, response to an intervention will not be considered to be an exceptional factor.

**Triage of requests for individual funding**

Individual funding requests will be accepted from doctors and, in certain circumstances, other registered health practitioners.

The treating clinician should complete the standard IFR form and submit it to the IFR Team. This requires responses to a common set of questions that will assist the CCG in determining if the patient is exceptional to the general policy.

**Photographic evidence**

Photographic evidence can be submitted in support of a patient’s Individual Funding Request. However, this can only be submitted by a clinician (not a patient) and must be signed on the back with the following wording: -

"I (Clinician’s name) confirm that this photograph is a true representation of (patient’s name) taken on (date photo taken) and has not been altered in any way."

The photo then needs to be signed and dated. The final decision as to whether photographs are viewed is at the request of the IFR Panel.

The completed form should be sent to NHS Greater Huddersfield CCG IFR Team:
Individual Funding Requests Team  
NHS Greater Huddersfield Clinical Commissioning Group (GHCCG)  
Broad Lea House, Bradley Business Park,  
Dyson Wood Way, Bradley  
Huddersfield  
HD2 1GZ  

Telephone: 01484 464062  
Email: GHCCG.IFR-CKW@nhs.net.  
Safe Haven Fax: 01484 464062  

The IFR Team will triage the request to see if the requested health care intervention is funded as part of a general policy. If this is the case, the treating clinician will be advised of the general policy and no further action will be taken.  

If the health care intervention is not funded as part of a general policy and the treating clinician has identified appropriate reasons why the patient may be considered to be exceptional to the policy, the triage process will pass the request on to the IFR process for consideration subject to appropriate timescales determined by the urgency of the request. If no claim of ‘exceptionality’ is made, the treating clinician will be advised of the general policy and no further action will be taken.  

With the exception of referrals for mental health care and/or treatment, the IFR Team will triage the request to see if the requested health care intervention is funded as part of a general policy. If this is the case, the treating clinician will be advised of the general policy and no further action will be taken.  

For mental health referrals, the commissioning manager (mental health) and a clinician (Nurse Consultant) from South West Yorkshire Partnership Foundation Trust (SWYPFT), as appropriate, will discuss and triage to make a recommendation about funding in line with the commissioning policy. This may involve viewing clinical records held by current providers to understand the services previously or currently accessed by the patient. This triage process ensures that the appropriate follow-on or initial treatment is offered to the patient, either via the IFR process or via commissioned services.  

Their decision along with a clear rationale will be communicated to the IFR Team who will retain responsibility for communicating the decision to the referrer, requesting further information from the referrer, or passing the request for IFR Panel consideration.  

Consideration of urgent requests  
The need to make urgent funding decisions should be minimised by horizon scanning and the proactive development of general policies in collaboration with provider
partners. However, occasionally clinical circumstances may require urgent use of a health care intervention that requires an individual funding decision.

While the CCG will endeavour to respond to such urgent requests as quickly as possible this should not compromise the quality and validity of the decision-making process.

The CCG accepts no responsibility for the clinical consequences of any delay in responding to the request.

The process below relates to the clinical urgency with which a funding decision must be made by the CCG:

• The urgency of the request will be determined by a senior member of the IFR Team, i.e. that the request must be processed quickly in order to avert, alleviate or avoid any perceived significant harm to the patient, which may arise unless a decision is taken in a shorter timescale than might otherwise be expected within the IFR process.

• Retrospective funding of any healthcare or treatment will not be funded unless prior approval has been given by the CCG or unless it can be demonstrated that the treatment was needed as an emergency or to avoid a life-threatening situation.

• All applications for treatment or funding that are deemed urgent will be acknowledged by telephone, fax or email on the day of receipt.

• A senior member of the IFR Team will make contact with the applicant to agree a timescale within which a response will be provided in order to meet the patient’s clinical need, this will be a maximum of 24 hours.

• Urgent requests will be considered by a Governing Body GP and senior manager from NHS Wakefield CCG who have been trained in the IFR process or through reciprocal arrangements in place with the NHS Greater Huddersfield CCG Exceptional Cases Committee.

• Urgent requests will be taken to the next available IFR panel to be ratified by panel members.

The Individual Funding Request Panel
The CCG has a panel, called the Individual Funding Request (IFR) Panel, whose members have specific training in the assessment of individual funding requests. Members of the IFR panel may include: executive directors, commissioning managers, consultants in public health, senior pharmacist, GPs and lay representative.

The IFR Panel will receive the request from the treating clinician together with any other relevant information. The patient and the treating clinician may submit additional information to the IFR Panel that they consider to be relevant and appropriate.

The CCG will keep the treating clinician and the patient informed at all times of the timescales for the process.

The treating clinician will receive a response to their request within the agreed timescale. In most cases, and providing all of the requested information was submitted, this will be with a decision on funding. However, if further information or clarification is needed the CCG will advise the treating clinician and the patient of the revised timescale for the decision.

The decisions made by the IFR Panel are recorded. The Panel’s decision may be to fund the individual request or not to fund the request. If a decision cannot be made the reasons will be made clear to the treating clinician and patient.

If the CCG decides to refuse a request to fund a health care intervention for an individual, where the CCG’s general policy is not to fund that treatment, the IFR Team will provide the patient with a written statement of the reasons for the decision.

The Chair of the Panel, or designated officer, will inform the treating clinician of the decision and, if requested, a copy of this information will be sent to the patient’s GP.

Principles for decision making
In making a decision, the Panel will, as a minimum, consider the following:
• Patient safety
• Clinical and cost effectiveness and strength of evidence
• Place in therapy relative to available health care interventions
• Affordability
• National guidance and priorities
• Local priorities
The best available evidence will be used to inform decisions.
Appealing against a decision not to fund

Where a decision has been made by an IFR Panel not to fund a health care intervention and the treating clinician feels that all relevant clinical information has been provided and considered the patient or their doctor may appeal against the IFR Panel decision. Information on how to do this will be provided by the CCG.

Appeals are referred to the IFR Appeals Panel. Membership of this Panel is different to the IFR Panel and will include IFR Panel members not involved in the original decision, and the Chief Officer or Clinical Chair of NHS Wakefield CCG. The Appeals Panel is able to access expert evidence as required including from independent clinicians.

An appeal against an IFR decision should be made within 3 months of the treating clinician receiving the IFR decision.

The IFR Appeals Panel provides a procedural review of the IFR Panel decision. The IFR Appeals Panel has access to the all relevant documentation about the request but does not, in general, consider new evidence.

Such review will include:

- Was due process followed? Did the CCG follow its own policies and procedures?
- Did the IFR panel take into account all of the relevant information available at the time?
- Was the decision reasonable and in line with the evidence?

Typically, the entire case will be received by the Appeals Panel on paper without either side being present. However, if in exceptional circumstances, the Appeals Panel believes that it would benefit the Panel to have one side present at the hearing, the other side will also be invited to attend.

The IFR Appeals Panel may decide to uphold the original decision, to reverse it (that is, agree to fund the health care intervention), or to ask the IFR Panel to reconsider its decision.

The Chair of the IFR Appeals Panel, or a designated officer, will inform the patient, the treating clinician, the CCG and, if requested, the patient’s GP, of the decision of the Appeals Panel.
If the IFR Appeals Panel upholds the original decision not to fund an intervention, the patient may choose to complain about the decision within the NHS complaints procedure.
## Appendix 6 – NHS Wakefield CCG Individual Funding Requests Referral Form

### Confidential

**Individual Funding Requests (IFR) - Submission form**

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<table>
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<tbody>
<tr>
<td>A</td>
<td><strong>NHS Number:</strong></td>
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<tr>
<td>B</td>
<td><strong>Prior approval procedure requested:</strong></td>
</tr>
<tr>
<td></td>
<td>Is this request clinically urgent (please give detail):</td>
</tr>
<tr>
<td>C</td>
<td><strong>Patient diagnosis:</strong></td>
</tr>
<tr>
<td>D</td>
<td><strong>Have you checked the CCG’s Commissioning Policy?</strong>&lt;br&gt;(Please request from the IFR Team if you require a copy)</td>
</tr>
<tr>
<td></td>
<td>Are you aware of the CCG’s eligibility criteria relating to this procedure?</td>
</tr>
<tr>
<td>E</td>
<td>Where eligibility criteria exist - does the patient meet the eligibility criteria outlined in the policy?</td>
</tr>
<tr>
<td></td>
<td>If yes – please provide relevant information relating to each of the eligibility criteria then proceed to section L:</td>
</tr>
<tr>
<td></td>
<td><strong>Please note, if you do not provide specific information to address all of the eligibility criteria in the policy this will lead to a delay.</strong></td>
</tr>
<tr>
<td></td>
<td>Where eligibility criteria do not exist or if the patient does not meet the eligibility criteria please complete the rest of this form.</td>
</tr>
<tr>
<td>F</td>
<td><strong>Detail standard interventions and alternative options tried (including costs where possible); why is this procedure the most appropriate treatment option for the patient?</strong></td>
</tr>
<tr>
<td>G</td>
<td><strong>Evidence base to support the request (including clinical opinion &amp; NICE etc):</strong></td>
</tr>
<tr>
<td>H</td>
<td>Evidence of exceptional circumstances related to this patient (address definition of exceptional circumstances):</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>I</td>
<td>Expected outcomes (including duration of treatment and frequency if relevant &amp; proposals for monitoring success):</td>
</tr>
<tr>
<td>J</td>
<td>Details of the proposed provider including costs of the requested treatment:</td>
</tr>
<tr>
<td>K</td>
<td>Any additional information:</td>
</tr>
<tr>
<td>L</td>
<td>Confirmation that the patient consents to their anonymised case being considered by an IFR Panel, if required and that as the requesting clinician you will ensure they are informed of the progress of the request. Yes/ No</td>
</tr>
</tbody>
</table>
| M | Date completed:  
Referring Clinician.  
Print name:  
Signature:  
Organisation:  
Position :  
Address:  
Phone number: |
| GP Practice if different: |
| If additional supporting information has been attached please indicate the number of pages …….
Access to infertility treatment

Commissioning Policy Document
Yorkshire and Humber

Implemented by NHS North Kirklees and Wakefield Clinical Commissioning Group

January 2017- January 2020
Commissioning Policy Statement:

Commissioning

This document represents the commissioning policy of North Kirklees Clinical Commissioning Group (NK CCG) for the clinical pathway which provides access to tertiary fertility services. This commissioning policy has been developed in partnership with the Yorkshire and The 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 North Kirklees CCG.

Funding

The number of full IVF cycles currently funded by the NK CCG for patients who meet the access criteria set out in the shared policy is one full cycle. This is unchanged from the previous funding policy in 2014. 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.

Panel Members:

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 West 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, NE 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 WillouNKby Lead for Planned Care, NHS Harrogate and Rural District CCG

Dr. Clare Freeman Medical Advisor to IFR Panel, South Yorkshire and Bassetlaw CCGs
Conflicts of Interest

See appendix D.

For Further Information about this policy;

Please contact North Kirklees Clinical Commissioning Group.
**Summary of CCGs in Yorkshire and Humber position with regards number of cycles in January 2017** (note this may be subject to change, please check with the individual commissioner for the current position):

<table>
<thead>
<tr>
<th>CCG</th>
<th>Age 18 - 40</th>
<th>Age 40 - 42</th>
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<tbody>
<tr>
<td>Airedale Wharfedale and Craven CCG</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Barnsley CCG</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Bassetlaw CCG</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Bradford District CCG</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Calderdale CCG</td>
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<tr>
<td>Doncaster CCG</td>
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<tr>
<td>East Riding of Yorkshire CCG</td>
<td>1</td>
<td>1</td>
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<tr>
<td>North Kirklees CCG</td>
<td>1</td>
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<tr>
<td>Hambleton, Richmond and Whitby CCG</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Harrogate and Rural District CCG</td>
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<tr>
<td>Hull CCG</td>
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<td>Leeds North CCG</td>
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<td>Leeds South &amp; East CCG</td>
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<tr>
<td>Leeds West CCG</td>
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<td>North Lincolnshire CCG</td>
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</table>
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1. **Aim of paper**

1.1 This document represents the commissioning policy of NHS North Kirklees and Wakefield Clinical Commissioning Groups (CCG), for the clinical pathway which provides access to tertiary fertility services. It is intended to provide a framework for the commissioning of services for those adults who are infertile and require infertility interventions.

1.2 The policy aims to ensure that those most in need and able to benefit from NHS funded treatment are given equitable access to tertiary fertility services, 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. In February 2013 NICE published revised guidance which was reviewed by NICE in 2016 and which updated previous NICE guidance published in 2004.

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:

**Definition of Infertility:**

For all couples: The presence of known reproductive pathology.

For heterosexual couples: The failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology.

For same-sex couples: the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI, in the absence of any known reproductive pathology.

For couples where one partner has a known medical condition: this must be a medical condition which prevents natural conception such as physical disability, an infection requiring sperm washing, or a severe psychosexual disorder.

Note - For couples where ovulation can be induced with simple techniques such as clomiphene, these patients are not regarded as infertile on this basis alone - and therefore would not meet the eligibility criteria for access to IVF at that stage.
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 remaining couples about a third of cases are due to the male partner being unable to produce or ejaculate sufficient normal sperm, a third are due to problems found with the female partner such as:

- Failure to ovulate
- Blockage to the passage of the eggs

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 Tertiary 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). All tertiary 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 40-42.

2.9 NHS North Kirklees and NHS Wakefield CCGs will fund one full cycle of IVF treatment. Where an individual feel that they have exceptional circumstances that
would merit consideration of an additional cycle being funded by the CCG they should speak to their clinician with regards to submitting an Individual Funding Request to NHS North Kirklees and Wakefield CCGs.

2.10 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.

   4.3 **Risks**

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

<table>
<thead>
<tr>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are risks of multiple pregnancies during fertility treatment, which is associated with a higher morbidity and mortality rate for mothers and babies.</td>
</tr>
<tr>
<td>Women who undergo fertility treatment are at slightly higher risk of ectopic pregnancy.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Current research shows no cause for concern about the health of children born as the result of assisted reproduction.</td>
</tr>
<tr>
<td>A possible association between ovulation induction therapy and ovarian cancer in women who have undergone treatment is uncertain.</td>
</tr>
</tbody>
</table>
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
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.

5.1.3 As infertility and infertility treatments have a number of psycho-social 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 (fig. 1)

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, prior to the commencement of assisted conception interventions, 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, 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.

- In relation to lifestyle factors, patients should be informed that the following reduces the effectiveness and / or success rates of assisted reproduction procedures, including IVF treatment;

  - more than 1 unit of alcohol per day
  - maternal and paternal smoking
  - maternal caffeine consumption

- Women who smoke should be offered referral to a smoking cessation programme to support their efforts in stopping smoking.

- Women should be informed that passive smoking is likely to affect their chance of conceiving.

- Men who smoke should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking will improve their general health, men who smoke should be offered referral to a smoking cessation programme to support their efforts in stopping smoking.

- Women who are trying to become pregnant should be informed that drinking no more than 1 or 2 units of alcohol once or twice per week and avoiding episodes of intoxication reduces the risk of harming a developing foetus. Appropriate advice and onward referral should be offered, where clinically appropriate.

- Men should be informed that excessive alcohol intake is detrimental to semen quality.
A number of prescription, over-the-counter and recreational drugs interfere with male and female fertility, and therefore a specific enquiry about these should be made to people who are concerned about their fertility and appropriate advice and onward referral should be offered, where clinically appropriate.

Appropriate advice and onward referral should be offered, where clinically appropriate to Lifestyle Services, using local arrangements to make a referral. 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. If a hand-held record is not available locally, use local protocols to record this information.

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 happening 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 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 tertiary care for assessment for assisted conception techniques, such as IVF, DI, IUI, and ICSI.

5.2.2 IVF involves:
- The use of drugs to switch the natural ovulatory cycle.
- Induction of ovulation with other drugs
- 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
- Use of progesterone to make the uterus receptive to implantation
- Transfer of selected embryos and freezing of those suitable but not transferred
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. (Not expected to be more than 4)

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

5.4 Frozen Embryo Transfers

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.

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 is 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)
Where a medical condition exists (such as physical disability, after sperm washing to prevent infectious disease transmission, or a severe psychosexual disorder prevents natural conception), IUI for up to 6 cycles 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. Treatment will be funded providing other criteria are met.

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 who meet the definition of infertility, 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.

5.6.4 Donor Gametes including azoospermia:
**Donor Sperm**
Up to six cycles of donor insemination (dependent on availability of donor sperm) will be offered for couples with male azoospermia via donor Sperm

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. Patients who require donor eggs 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 are still met.

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 the woman/couple may self-fund continued storage.

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 embryos 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 the CCG, but we will 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 tertiary 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 therefore recommends that steps are taken by providers to minimize multiple births. 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 tertiary 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 tertiary care (with the exception of 6.9, which should be undertaken within tertiary care). Couples must meet the definition of infertility as described in section 2.3.

6.2 Overarching Principles

6.2.1 Eligibility criteria should apply equally to all assisted conception treatments (IUI, IVF, and ICSI).

6.2.2 All clinically appropriate individuals/couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. Only couples meeting the eligibility criteria should be referred to tertiary care.

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 one full cycle of IVF, with or without ICSI, provided the following 3 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 BMI
6.5.1 The female patient’s BMI should be between 19 and 30 prior to referral to tertiary services. Female patients with a higher BMI should be informed that a BMI outside of this range is likely to reduce the success of assisted reproduction procedures. Female patients who have a BMI of 30 or over and who are not ovulating should be informed that losing weight is likely to increase their chance of conception. Patients should therefore be referred for healthy lifestyle interventions including the local weight management programme. Patients should not be re-referred to tertiary services until their BMI is within the recommended range.

6.5.2 Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility and should therefore be referred for healthy lifestyle interventions including the local weight management programme.

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 self-funded or NHS funded couples
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 of 3 full cycles that may be offered by the NHS. This includes where any one person in the couple has had a previous NHS funded
cycle with a previous partner. The allocation is per person and per couple, so a previous cycle for one person in the couple will count towards their NHS funding allocation.

6.8 Length of relationship
Cohabiting couples must have been in a stable relationship for a minimum of 2 years to be entitled to treatment.

6.9 Welfare of the child
The couple should be assessed as meeting the requirement contained within the HFEA Appendix entitled 'Welfare of the child'.

7.0 Exemptions
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 will no longer be included in the scope of services available for free for those who pay the immigration health surcharge.

**Appendix, A**

**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviations used</th>
<th>Full Form</th>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>DI</td>
<td>Donor Insemination</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HFEA</td>
<td>Human Fertilisation and Embryology Authority</td>
</tr>
<tr>
<td>ICSI</td>
<td>Intracytoplasmic sperm injection</td>
</tr>
<tr>
<td>IUI</td>
<td>Intra-uterine insemination</td>
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<td>IVF</td>
<td>In vitro fertilisation</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute of Clinical Excellence</td>
</tr>
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<td>CCG</td>
<td>Clinical Commissioning Group</td>
</tr>
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### Contents

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Further information</th>
</tr>
</thead>
</table>
| 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](http://www.bbc.co.uk)  
NHS Direct [http://www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)  
Glossary, HFEA [http://www.hfea.gov.uk](http://www.hfea.gov.uk) |
| ICSI   | **Intra Cytoplasmic Sperm Injection (ICSI)**: Where a single sperm is directly injected into the egg.                               | As above                                                  |
| 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                                                  |
## Title of policy
Access to infertility treatment, Commissioning Policy

## Names and roles of people completing the assessment
Fiona Day Consultant in Public Health Medicine, and Associate Medical Director Leeds West CCG, on behalf of YH fertility panel

## Date of Assessment from - to
3.3.17 - 3.3.17

### 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

### 3. Consultation, engagement

Give details of all consultation and engagement activities used to inform the
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](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

<table>
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<th>Are there any likely impacts?</th>
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<td>Other relevant group</td>
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If any negative/positive impacts were identified are they valid, legal and/or justifiable?

CCGs have a duty under the Equality Act 2010 to:
(a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
(b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who
Please detail.

| do not share it; |
| (c)foster good relations between persons who share a relevant protected characteristic and persons who do not share it. It also has responsibilities under the Public Sector Equality Duty to have due regard to the need to advance equality of opportunity. |
| Overall the policy will have a positive impact on all the 9 protected characteristics. |

This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility.

As stated in NICE CG156 guidance all couples without known reproductive pathology are required to test their fertility and meet a threshold definition of unexplained infertility before they will be eligible for funded tertiary treatment. This is defined in 2.3:

For couples that do not have identified fertility pathology preventing them from conceiving there are two options available to enable them to test their fertility to access tertiary services:

   For all couples: The presence of known reproductive pathology.

   For heterosexual couples: The failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology.

   For same-sex couples: the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI, in the absence of any known reproductive pathology.

   For couples where one partner has a known medical condition: this must be a medical condition which prevents natural conception such as physical disability, an infection requiring sperm washing, or a severe psychosexual disorder.

   Note - For couples where ovulation can be induced with simple techniques such as clomiphene, these patients are not regarded as infertile on this basis alone - and therefore would not meet the eligibility criteria for access to IVF at that stage.

The requirement to self-fund will have an adverse financial impact on same-sex couples. It is likely that the number of same-sex couples affected is likely to be proportionately higher. It is also recognised that for same-sex couples there are innate biological issues which affect the couples' own resources to access the policy.

This policy relates to access to infertility treatment, i.e. tertiary services for those who have identified fertility
problems (whether known reproductive pathology, physical disability or unexplained fertility as defined in the NICE CG156 guidance. The CCGs consider that NHS financial resources in this area should be directed to meeting the medical needs of those with identified fertility problems. If the CCG were to fund IUI for couples who did not have identified fertility problems, significant NHS resources would be being spent on treatment for individuals who do not have (and proportionality are not likely to have) an identified fertility problem which would require tertiary treatment on the grounds of infertility. The CCGs have also considered discriminating against heterosexual couples in this regard.

The CCG considers that appropriate focusing of scarce NHS resources is a legitimate aim, and that not providing funding of IUI treatment in these circumstances is a proportionate means of achieving that aim having regard to the rest of the policy and broad access for all couples with identified fertility problems. The innate barriers to conception are known in same-sex couples and are therefore something that can be planned for in advance. Alternative restrictions would involve reducing funding to individuals with identified fertility problems (in heterosexual, same-sex female and same-sex male couples) or other clinical areas and the CCGs do not consider that funding this treatment outweighs other demands on NHS resources.

CCGs will always consider exceptional cases on an individual basis via their Individual Funding Request process.

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.

This is a policy for couples to access fertility treatment, it is not a policy to provide conception for single adults.

Information on fertility services will be provided in a wide range of formats to meet the diverse needs of couples.

- Face to face discussions with couples

- Written information and advice

- Culturally sensitive

Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.
## 5. Monitoring, Review and Publication

<table>
<thead>
<tr>
<th>How will you review/monitor the impact and effectiveness of your actions</th>
<th>Each CCG to monitor individual funding requests for this procedure and identify if there are issues with the policy which require a policy refresh.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Officer</td>
<td>Fiona Day</td>
</tr>
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## 6. Sign off on behalf of the local CCG

<table>
<thead>
<tr>
<th>Lead Officer</th>
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<tr>
<td>Director</td>
<td><strong>Date approved:</strong></td>
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## Appendix D, Version Control

<table>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Status</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Review 2017</td>
<td>22.2.17</td>
<td>F Day on behalf of</td>
<td>Final</td>
<td>- changes to the definition of infertility for same sex and patients with psychosexual issues and disabilities to be more clear</td>
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<tr>
<td></td>
<td></td>
<td>panel</td>
<td>draft</td>
<td>- the addition of public health requirements for providers in line with NICE guidance</td>
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<td></td>
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<td></td>
<td></td>
<td>- clarification of the definition of an abandoned cycle</td>
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<td></td>
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<td></td>
<td>- sections on intrauterine insemination and also egg donation updated in line with NICE guidance</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 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</td>
</tr>
</tbody>
</table>
Appendix E 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.
## Appendix 8 – Equality Impact Assessment Checklist Tool

<table>
<thead>
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<th>Commissioning Policy</th>
<th>Yes/No</th>
<th>Comments</th>
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<tbody>
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<td>1</td>
<td>Does the policy/guidance affect one group less or more favourably than another on the basis of:</td>
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<td></td>
<td>• Race</td>
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<td></td>
<td>• Ethnic origins (including gypsies and travellers)</td>
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<td>• Disability - learning disabilities, physical disability, sensory impairment and mental health problems</td>
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<td>3</td>
<td>If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?</td>
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<td>5</td>
<td>If so can the impact be avoided? N/A action?</td>
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<td>6</td>
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