NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Bunions, surgical removal

Category 2 Intervention - Only routinely commissioned when specific criteria are met -

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
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1. Introduction

1.1 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

1.2 This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined in Appendix 1.

1.3 At the time of publication, the evidence presented per procedure/treatment was the most current available.

2. Purpose

2.1 This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

3. Policy statement

3.1 Surgical removal of bunions (hallux valgus) is not routinely commissioned for cosmetic reasons alone.

3.2 Patients may be referred for a surgical opinion if all of the following criteria have been satisfied:

3.2.1 They have failed to respond to at least 3 months of conservative treatments. (These include footwear modification, bunion pads, insoles, simple analgesics, orthotics, physiotherapy).

AND

3.2.2 Experience pain under the ball of the foot and/or functional disability.

4. Exclusions

4.1 None

5. Rationale

5.1 The policy statement is in accordance with the commissioning guide on painful deformed great toe in adults produced by the Royal College of Surgeons.

6. Underpinning evidence

6.1 *Hallux valgus* is a deviation of the big toe towards the adjacent toes where a bony protrusion (the "bunion") is formed by medial deviation of the first metatarsal phalangeal joint.[1] The skin may be damaged in the area of the bunion causing pain on walking, difficulty with footwear and concerns about its appearance. In some cases, the deformity may contribute to impaired balance with an increased incidence of falls. If left untreated in patients with diabetes, ulceration, deep infection and in extreme cases, the requirement for a below knee amputation.[2] If there is stiffness in the joint with difficulty in moving the big toe, the condition is termed *hallux rigidus*.[3] Bunions may be caused by the wearing of poorly fitting shoes (particularly narrow ones) or arthritis or may have been inherited.

6.2 The prevalence has been reported to be 28.4% in adults older than 40 years, is higher in women and increases with age.[2] Other reports cite the prevalence as 23% in adults aged 18 – 65 years and 35.7% in people aged 66 years or older.[4]

6.3 Surgical correction of hallux valgus was first described in 1836.[5] There are many surgical techniques but the 3 main categories are fusion of the joint (arthrodesis), simple excision (e.g. Keller's procedure) and joint replacement with an artificial implant.[3] Surgery may be required in patients with severe symptoms who do not respond to more conservative measures. The literature is awash with different techniques but there is limited evidence to differentiate between them and more high quality, comparative studies are required.[6,7] It is also apparent that minimally invasive techniques for bunions have failed to disseminate into common UK practice.[8]

6.4 Conservative, nonsurgical measures include footwear modification, use of insoles or toe spacers/pads.[1] Footwear modification involves wearing wider fitting shoes with low heels. In addition, other measures include over-the-counter analgesics, ice to relieve pain and inflammation, physiotherapy and orthotics.[2]

6.5 The most authoritative guideline in the UK (2017) on management was developed by the British Orthopaedic Foot & Ankle Society and the British Orthopaedic Association under the auspices of the Royal College of Surgeons.[2] This expresses the expectation that the vast majority of patients will be managed in primary care. Referral to a specialist provider may be warranted in cases of deteriorating symptoms, functional impairments, inability to wear suitable shoes or pain under the ball of the foot. In no circumstances, should referrals be made for cosmetic reasons only. The Royal College recommends referral for surgery in the following circumstances:

- deteriorating symptoms,
- no response to conservative measures after 3 months,
- persistent pain and disability which hasn't responded to 12 weeks of nonsurgical treatments,
- patients understand and accept the need to be off their feet for several weeks post operatively.

6.6 Similar recommendations were adopted by NHS England in its interim clinical commissioning policy (2013) on bunion surgery prepared by the Armed Forces Commissioning Policy Task and Finish Group.[9] Although this only applies to the Armed Forces, the policy is similar to above in that surgery is only indicated when conservative methods have failed and where the deformity is causing significant functional impairment or the patient is in severe pain.

6.7 In summary, hallux valgus (more commonly known as bunion) is a deviation of the big toe caused by a malformation in the metatarsal phalangeal joint. This is very common (in at least 20% of the general population) and rises with age. Although the evidence base isn't extensive, it is generally accepted that surgery should be reserved for those patients who haven't responded to more conservative measures (such as modification of footwear, analgesics, orthotics etc) and who are experiencing severe functional difficulties and/or pain. Neighbouring CCGs have very similar policies.

7. References

1. Surgical correction of hallux valgus using minimal access techniques: National Institute for Health and Care Excellence, 2010:IPG332.

2. Commissioning guide: painful deformed great toe in adults Version 1.1. *Royal College of Surgeons of England (RCS)* 2017

3. Metatarsophalangeal joint replacement of the hallux: National Institute for Health and Care Excellence, 2005:IPG140.

4. Prevalence of hallux valgus in the general population : a systematic review and meta-analysis. *BioMed Central* 2010

5. Smyth NA, Aiyer AA. Introduction: Why Are There so Many Different Surgeries for Hallux Valgus? *Foot and ankle clinics* 2018;**23**(2):171-82. doi: 10.1016/j.fcl.2018.01.001

6. Klugarova J, Hood V, Bath-Hextall F, et al. Effectiveness of surgery for adults with hallux valgus deformity: a systematic review. *JBI database of systematic reviews and implementation reports* 2017;**15**(6):1671-710. doi: 10.11124/JBISRIR-2017-003422

7. Ferrari J. Bunions. *BMJ Clin Evid* 2009;**2009** [published Online First: 20090311]

8. Harrison WD, Walker CR. Controversies and Trends in United Kingdom Bunion Surgery. *Foot and ankle clinics* 2016;**21**(2):207-17. doi: 10.1016/j.fcl.2016.01.001

9. Interim clinical commissioning policy: bunion surgery. London: NHS England, 2013:N-SC/007.

8. Force

8.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

9. Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
Any in primary position

W791	Soft tissue correction of hallux valgus
W792	Excision of bunion NEC
W799	Unspecified soft tissue operations on joint of toe
W151	Osteotomy of neck of first metatarsal bone
W152	Osteotomy of base of first metatarsal bone
W153	Osteotomy of first metatarsal bone NEC
W154	Osteotomy of head of metatarsal bone
W155	Osteotomy of midfoot tarsal bone
W158	Other specified division of bone of foot
W159	Unspecified division of bone of foot
W591	Fusion of first metatarsophalangeal joint and replacement of lesser metatarsophalangeal joint
W592	Fusion of first metatarsophalangeal joint and excision of lesser metatarsophalangeal joint

W593 Fusion of first metatarsophalangeal joint NEC
W594 Fusion of interphalangeal joint of great toe
W595 Fusion of interphalangeal joint of toe NEC
W596 Revision of fusion of joint of toe
W598 Other specified fusion of joint of toe
W599 Unspecified fusion of joint of toe
W793 Syndactylisation of lesser toes
W798 Other specified soft tissue operations on joint of toe

9.2 **International classification of diseases (ICD-10)**

With or without any position
M201 Hallux Valgus (acquired)
M203 Other deformity of hallux (acquired)
M205 Other deformities of toe(s) (acquired)
M206 Acquired deformity of toe(s), unspecified

Excluding in any position
M202 Hallux rigidus
M204 Other hammer toe(s) (acquired)

10. Monitoring And Review

10.1 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

10.2 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

11. Quality and Equality Analysis

11.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

Appendix 1 - Core Objectives and Principles

Objectives

The main objective for having healthcare commissioning policies is to ensure that:

- Patients receive appropriate health treatments
- Treatments with no or a very limited evidence base are not used; and
- Treatments with minimal health gain are restricted.

Principles

This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

- Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
- Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
- Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
- NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

Cosmetic Surgery

Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

A summary of Cosmetic Surgery is provided by NHS Choices. Weblink:
http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and
http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

Diagnostic Procedures

Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

Clinical Trials

The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

Clinical Exceptionality

If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy.