Clinical Commissioning Policy:

Direct Skeletal Fixation for transfemoral limb loss (adults) [2206]

Summary

Direct Skeletal Fixation is not recommended to be available as a routine commissioning treatment option for transfemoral limb loss.

The policy is restricted for use in adults to avoid disruption of the growth plate in younger patients.

Committee discussion

Clinical Panel considered the evidence base and the recommendation was made to progress the policy. Please see the Clinical Panel report for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed here:(Link to be added at publication).

What we have decided

NHS England has carefully reviewed the evidence to treat Direct Skeletal Fixation in patients with transfemoral limb loss. NHS England recognises that the published evidence identifies that, at present, there is sufficient evidence to commission this treatment. However, following the relative prioritisation process undertaken in May 2024, NHS England has concluded that, balanced against other relative priorities that were also considered during this process, direct skeletal fixation for transfemoral limb loss will not be funded at this time within the resources available.

The evidence review can be accessed here: [Link to be added at publication].

Links and updates to other policies

This document updates a not routinely commissioned policy statement that was published in February 2019, for Osseointegration for Transfemoral Amputation in Adults. This can be accessed: 1628-cc-policy-statement-osseointegration-for-transfemoral-amputation-adults.pdf (england.nhs.uk).(NHS England, 2019).

This current policy is linked to the Service Specification D01/S/d for Complex Disability Equipment – Prosthetic Specialised Services for People of All Ages with Limb Loss.

Plain language summary

About transfemoral limb loss

Transfemoral limb loss refers to limb deficiency through the knee or above, either from birth or due to amputation. The majority of lower limb amputations are a consequence of peripheral arterial disease; other causes include trauma, diabetes and tumour. Lower extremity amputation has profound implications for a patient's functional capability, mobility, and quality of life.

About conventional socket prostheses

Following surgery, the current treatments for amputees are custom sockets attached to a prosthetic limb. The type of prosthesis that is recommended will depend on patient-specific factors and the type of amputation. For any prosthesis, prolonged physiotherapy and rehabilitation is required and therefore this is not a suitable option for every patient. Friction between the residual limb and socket can cause pain and skin breakdown, and for the patients who experience these complications the current alternative is the use of mobility aids such as crutches or a wheelchair. This can lead to, or make worse, pre-existing conditions including obesity, diabetes, vascular disease, osteoporosis, and mental health conditions.

About direct skeletal fixation

Direct skeletal fixation (DSF) is a form of surgery, also known as osseointegration, which replaces the need for an amputee to wear a socket upon which normally a prosthesis would be attached. It involves placing an implant (a rod usually made of titanium) through the skin into the bone which may be carried out in two separate operations or as a single operation. In the first stage, the implant is inserted into the central part of the remaining bone. The second stage of the procedure is undertaken either during the same operation or approximately 3 – 6 months later, after the wound has completely closed and has healed and the implant has set into the bone. The second stage involves connecting the implant to a small metal extension which goes through the skin, allowing the prosthetic limb to be attached to the implant within the bone. A period of rehabilitation follows during which a training prosthesis is used.

Patient selection should be carried out by a multidisciplinary team (MDT), including a surgeon experienced in amputation and bone and soft tissue reconstruction as well as rehabilitation specialists, with expertise in prosthetics and implant design.

Epidemiology and needs assessment

A study of all transfemoral amputation procedures in England 2003-2008 found that there were 13,500 procedures undertaken in this time period (12,800 above the knee and 700 through the knee) which equates to 2,300 transfemoral amputations per year (Moxey et al, 2010). A subsequent study covering a 10-year period 2003-2013 reported 22,600 lower limb amputations above the knee amputations, equating again to 2,300 transfemoral amputations per year (Ahmad et al, 2016). In England, the aetiology of lower limb amputations is as follows: vascular disease 90%, trauma 5%, neoplasm 1%, other causes 4% (Stewart and Trimming, 2008). This figure of 2,300 is likely to have improved in recent years because of improved diabetic and peripheral vascular disease management, and access to interventional radiology. Therefore, of approximately 2,000 transfemoral

amputations per year, 120 are secondary to trauma or neoplasm and amputations of other aetiologies are excluded from this policy.

A literature search and analysis of patients referred to UK prosthetic services estimates that 60% of those with transfemoral amputation are too infirm for referral to limb fitting so 40% would be referred for prosthetics (Stewart and Trimming, 2008). Therefore, of 120 possible patients with transfemoral amputations due to trauma or neoplasm, 48 would be referred to prosthetic services.

The above analysis of UK prosthetic services notes that 4500 patients with limb loss at any level were referred to limb fitting services in 1997-1998, and also notes that about 1% of those referred to the UK prosthetic services have a congenital limb deficiency (Stewart and Trimming, 2008). Therefore 45 patients with congenital limb deficiency at any level would have been referred. Transfemoral limb loss made up 8.8% of all referrals that year, so roughly 8.8% of 45 patients with congenital limb deficiency are relevant to this policy, which is 4 patients.

Therefore, up to 52 patients per year may meet the initial policy criteria of transfemoral amputation or limb loss due to trauma, malignancy or congenital limb loss who are referred to limb fitting teams. However, the majority of these patients will tolerate conventional sockets, and it is only those who cannot who are relevant to this policy. There will also be a backlog of up to 100 patients from previous cohorts who meet these criteria as estimated by clinical consensus.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Full skeletal maturity	Skeletal maturity can be evaluated from the size and shape of bones and the degree of mineralisation or ossification. When the bone is fully mature, there is no longer potential for longitudinal growth.
Acquired amputation	Amputation as a result of trauma or surgery
Congenital absence (congenital deficiency)	Patients born without a limb due to a genetic condition
6 minute walk test	Distance in metres a patient can mobilise; a validated measure of functional capacity in amputees
TUG test	Timed up and go test; the time taken in seconds for a patient to mobilise without assistance from sitting to standing, walk 3 metres, walk back, and sit down.

References

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