Engagement Report

Topic details

Title of policy or policy statement:	**Direct Skeletal Fixation for people with transfemoral limb loss**
Programme of Care:	Trauma
Clinical Reference Group:	Rehabilitation, disability and spinal cord injury
URN:	2206

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. The clinical commissioning policy proposition went out to stakeholder testing between 27th March 2023 to 14th April 2023.

2. Background

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 conventionally a prosthesis would be attached.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks 27th March 2023 to 14th April 2023, accounting for bank holidays. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Have you read the Policy Proposition for Direct Skeletal Fixation for transfemoral limb loss 2206?
- Did you read the full evidence review?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details
- Did you read the Evidence to Decision?

- Do you support the Equality and Health Inequalities Impact Assessment? Any comments?
- Does the Patient Impact Assessment present a true reflection of the patient and carers lived experience of this condition? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Adult patients with transfemoral limb loss as the result of either acquired amputation or congenital absence (congenital deficiency) who are unable to tolerate conventional socket use
  Do you agree with this criterion? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Assessment by an MDT including a Consultant Orthopaedic Surgeon, a Consultant Rehabilitation Physician, a Specialist Physiotherapist, a Clinical Psychologist, a Specialist Occupational Therapist, and a Specialist Prosthetist who endorse the intervention in this patient
  Do you agree with this criterion? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Patient has actively participated in the limb fitting process
  Do you agree with this criterion? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Patient has full skeletal maturity
  Do you agree with this criterion? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Able to participate in a 6 week extensive physiotherapy and rehabilitation programme post operatively
  Do you agree with this criterion? Any comments?
- Patients may be referred if they fulfil ALL of the following criteria:
  Suitable for surgery based on medical history and physical anatomy
  Do you agree with this criterion? Any comments?
- Active deep tissue infection in target limb.
  Do you agree with this exclusion criterion? Any comments?
- Diabetic
  Do you agree with this exclusion criterion? Any comments?
- Weight over manufacturer limit for the device
  Do you agree with this exclusion criterion? Any comments?
- Chronic regional pain syndrome (CRPS), previous or current, due to risk of recurrence of CRPS post operatively, and potential for surgery to worsen symptoms of CRPS
  Do you agree with this exclusion criterion? Any comments?
- Inability or refusal to participate in post implant rehabilitation
  Do you agree with this exclusion criterion? Any comments?
- Severe osteoporosis
  Do you agree with this exclusion criterion? Any comments?
- Current smoker [due to associated vasculopathy and risk of implant failure]
  Do you agree with this exclusion criterion? Any comments?
- Peripheral vascular disease [as cause for amputation]
  Do you agree with this exclusion criterion? Any comments?
- Concerns from MDT regarding patient's ability to psychologically tolerate implants protruding through skin
  Do you agree with this exclusion criterion? Any comments?
- Amputation distal to through knee disarticulation
  Do you agree with this exclusion criterion? Any comments?

- Previous radiotherapy to the target femur, including groin and knee
  Do you agree with this exclusion criterion? Any comments?
- Current immunosuppression (the level of immunosuppression which would preclude treatment with this intervention is determined by the MDT who will be providing the treatment. Immunosuppression describes both primary or secondary, which can be due to treatments including but not limited to; systemic steroids, chemotherapy and anti-cancer medication, anti-tumour necrosis factor therapy, methotrexate, interleukin-6 inhibitors)
  Do you agree with this exclusion criterion? Any comments?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.
- Do you have any potential conflict of interest relating to this document or service area?

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care agreed that the proposition is for routine commissioning and does not require further public consultation. This has been assured and supported by the Patient Public Voice Advisory Group.

4. Engagement Results

There were 19 who responded to the stakeholder testing: 9 organisations, 1 of which had two clinicians who responded, and 10 individuals.

Of the respondents, all supported the proposition, and the majority supported each of the inclusion and exclusion criteria. Some feedback was raised about some of the criteria, which are addressed below.

How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group. The following themes were raised during engagement with registered stakeholders:

Keys themes in feedback	NHS England Response
Inclusion criteria	
Concerns were raised regarding what is meant by patients being “unable to tolerate conventional socket use” and how this would be assessed. Similar concerns were raised regarding the inclusion criterion “patient has actively participated in the limb fitting process”	PWG discussed the wording around these two criteria and has made changes to the policy proposition for clarity and to enable accurate patient assessment by centres.
Some organisations responded highlighting that not all limb fitting centres would have the required members of MDT for assessment	Only centres with the appropriate composition of the MDT will be commissioned to deliver the service; patients may need to be referred to these centres for consideration.
Some disagreement from responding organisations about the inclusion criterion requiring patients to be majority wheelchair users	The evidence review highlighted that patients who were predominantly wheelchair users had the biggest change in outcomes measuring clinical effectiveness post-intervention. Given the risks associated with the procedure, PWG

	feels it should be limited to those with the highest possible benefit.
Exclusion criteria	
Some organisations and individuals wanted diabetic patients to be included in the policy	Because of the risk of infection associated with the procedure, all papers included in the evidence review excluded patients with diabetes. Therefore, there is no evidence of clinical effectiveness or safety in this intervention among diabetic patients and therefore a policy cannot be written for this group.
Given that weight over manufacturer recommended weight limit for device is an exclusion criterion, concerns were raised regarding what guidance exists for if patients gain weight post operatively	PWG agree that this question requires addressing and a footnote has been added into the policy proposition.
Some organisations and individuals wanted patients with chronic regional pain syndrome (CRPS) to be included in the policy	Clinical consensus from PWG considers there is a high risk of CRPS recurrence post-operatively and this risk outweighs the benefit of the procedure in this group.
Some organisations and individuals wanted clarification on severity of osteoporosis	PWG agree that a cut off T score should be provided to enable MDTs to assess whether a patient meets this criterion, and this has been updated in the exclusion criteria.
The smoking exclusion criterion was felt to be unclear in terms of how long a patient should stop before being considered	PWG agree further evidence-based guidance on this is required, as smoking impairs wound healing, and the criteria have been updated accordingly with references.
The amputation level exclusion criterion “Amputation distal to through knee disarticulation” was felt to be unclear as the title refers to transfemoral amputations only	PWG agree that this requires clarification; given that the majority of the papers in the evidence review only include transfemoral amputations and not amputations at the level of the knee disarticulations, the criteria have been updated to reflect that only transfemoral amputations should be included and not amputations at the level of the knee disarticulation.
Rehabilitation pathway	
Several organisations had queries on the location of the supervised rehabilitation period as well as the long term follow up arrangements and ongoing patient care	PWG have considered this carefully and policy proposition was updated with additions to rehabilitation section for clarify. PWG re-emphasise that the initial phase of rehabilitation must be supervised due to requirement for loading under strict control and this is reflected in the papers included.

The responses should answer all the themes reported in section 4 and cover the outcome of reviews of any additional evidence highlighted during engagement

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following changes were made to the policy proposition and have been reviewed by core members of the PWG:

- Inclusion criteria
    - The second inclusion criterion has been updated to state: Patient is unable to mobilise using a conventional socket (confirmed by clinical assessment) despite having actively participated in the limb fitting process

at their local limb fitting centre for at least 12 months. This includes participation in the pre limb fitting process and engagement with the prosthetic team for rehabilitation, pain management, as well as participation in management plans regarding any issues with the sockets that have been trialled.

- Exclusion criteria
    - A footnote has been added to the “Weight over manufacturer limit for the device” exclusion criterion to guide MDTs to advise patients not to use the prosthetic if weight increases after the procedure to the extent that the weight exceeds the manufacturers recommended limit
    - Definition of current smoker has been added and referenced accordingly: A “non-smoker” in this instance is defined as someone who has never smoked or who has successfully quit smoking for at least 4 to 8 weeks prior to the procedure (WHO, 2020) (National Centre for Smoking Cessation and Training, 2020)(NICE, 2021).
    - Level of amputation has been clarified: patients should be excluded if amputation is distal to transfemoral amputation level
    - Severe osteoporosis definition has been added: as defined by a Bone Mineral Density T score of < -3.5 standard deviations (Gregson et al, 2022)
- Stopping criteria
    - The following criterion has been added: During the assessment process, patient weight increases such that it exceeds manufacturer limit for the device
- Monitoring and rehabilitation
    - Updated description of rehabilitation pathway and requirements
    - Updated location of ongoing care and follow up, including stoma care
    - Updated surgical follow up requirements are outlined

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.