NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 15 February 2023

Intervention: Direct Skeletal Fixation

Indication: Transfemoral limb loss (adults)

URN: 2206

Gateway: 2, Round 2

Programme: Trauma

CRG: Rehabilitation & Disability

Information provided to the Panel

Policy Proposition

Clinical Priorities Advisory Group Summary Report

Equalities and Health Inequalities Assessment (EHIA)

Patient Impact Assessment (PIA) Report

Evidence Review by Solutions for Public Health

Evidence to Decision Making Summary

Blueteq™ Form

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning of direct skeletal fixation (DSF) for adults with transfemoral limb loss – through knee or above, either from birth or due to amputation. These adults are unable to tolerate conventional socket use and have no alternative prosthetic treatment options. DSF is a form of surgery, also known as osseointegration. The proposition was previously considered at Clinical Panel in December 2022 who requested extensive revisions.

Clinical Panel was presented with an overview of the treatment and the evidence review supporting the proposition to refresh the position.

Each of the amendments requested by Panel, as highlighted in the previous Clinical Panel report, were considered in turn. The revisions to the proposition have been clearly highlighted. Panel members agreed that significant revisions had been made to the proposition and Blueteq™ form which sufficiently addressed the previous concerns.

It had previously been estimated that 100 people per year would be eligible for this procedure. It was not clear how this estimate had been arrived at and Panel members were previously concerned that the proposition may allow for a wider population to access. Revisions have been made to the Epidemiology and Needs Assessment section of the proposition. These better reflect the eligible population and that the estimate of those eligible per year was likely to be 52 or lower once the initial backlog of patients had been treated.

As this proposition is related to an IDEAL framework pilot, members were asked to consider whether the staging of development of the technique (2b) was useful to help inform decision making.

EHIA – it was raised that there is a strong link with military personnel and veterans, and this is not currently reflected. The EHIA needs updating to consider this group also to ensure they are not disadvantaged.

PIA – no amendments recommended.

Recommendation

Clinical Panel recommends this proceeds as a routine commissioning policy proposition.

Why the panel made these recommendations

Clinical Panel members considered that the revisions made to the proposition were sufficient to address previous concerns and had made the proposition much clearer.

Documentation amendments required

Policy Proposition:

- Exclusion criteria:
    - Immunosuppression – it needs to be stated that this is a consideration of the multi-disciplinary team as to the level of significance of such treatment when considering inclusion/exclusion. The level of immunosuppression therapy as an exclusion needs to be defined.

EHIA:

- Consideration needed to include military personnel and veterans to ensure they are not disadvantaged in any way.

Declarations of Interest of Panel Members: One member stated that they had been involved in the military.

Panel Chair: Anthony Kessel, National Clinical Policy Team Director, Specialised Services

PWG Post Panel Comments and document amendments

- Policy proposition: exclusion criterion of immunosuppression has been clarified. It now reads *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)*
- EHIA: Military veterans and military personnel have been added under “other”. The section now reads: *Military veterans and military personnel may be affected by traumatic amputations. Commissioned providers should work with the patient and other relevant agencies, in this case, agencies who look after military veterans and military personnel.*