NHS England

Clinical Commissioning Policy: Multi-grip Upper Limb Prosthetics

Reference: NHS England D01/P/c

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Additional Circulation List	Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing
Description	NHS England has adopted a policy to not routinely commission this specialised treatment as described in this document.
Cross Reference	
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	
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Document Status

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1 Executive Summary

Policy Statement

NHS England does not routinely commission multi-grip upper limb prosthetics, in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Upper Limb Amputees are routinely offered amputee rehabilitation and enablement via prosthetics including cosmetic arms and functional arms. The latter can be by body powered limbs (where a cord opens the hand in one simple motion when pulled by the shoulder or the opposite shoulder, attached by a loop to the other end of the cord) or myo-electric (where there are sensors that activate a motor or motors to open the hand in either 1 grip or multiple).

The benefits of myoelectric prosthetic hands are:

1. Better reach as not tethered to the other shoulder
2. Better control of both arms as no cord tension to adjust to.
3. Less overuse injuries of the other arm
4. Able to operate in all planes as not restricted to need for tension on the op cord to operate prosthesis. EG the split hook cannot be operated when close to the body as the op cord is not in tension.

The benefits of multi-articulating prosthetic hand and digits:

1. More than 1 grip possible. Up to 24 different grips are possible allowing appropriate grip for appropriate task
2. Natural movement of hands, i.e. independently moving digits rather than linear opening and closing
3. Addition of communication benefit with programmable hand with independently moving digits, hand signs such as the 'OK' and thumbs up can be programmed in to allow improved non verbal communication (70% of communication is non verbal)
4. Natural shape to the hand with multi-articulating hands rather than single grip hands, this is especially so for partial hand amputees
5. For digit amputation especially thumb amputation or deficiency there is no other option for functional prosthetics than the x-finger for multi grip
6. Due to precision and variety of grips the prosthesis is able to be used without the support of the other hand. Single grip myoelectric prostheses often require the placing of an object in its grasp by the other hand. There occupying both hands to participate in a single activity

2 Introduction

The function of the upper limbs is to interact with the environment. The majority of this interaction is via the hand that acts to manipulate objects. The hand also functions to aid non-verbal communication such as hand gestures.

The functioning upper limb depends on control and adaptability. The function of the upper limb amputee depends on training and functional aspects of the prosthesis. It

has been well recognised that upper limb prosthetic users should be supplied with both functional prostheses, i.e. body powered and myoelectric if they are able to control the prosthetics. Abandonment of prosthetics is lower with myoelectric compared to body powered prostheses.

Myo-electic prosthetics has developed significantly in the last 10 years. Previous to this the myo-eletric prosthetics were simple open and close devices. The development of the multi-grip hand with 5 independently moving digits (manual abduction and adduction of the thumb), followed recently by fully controlled thumb movement, was a field change in myoelectric prosthetic hands.

The development of prosthetic fingers allows powered multi grip patterns previously unavailable to finger and partial hand amputees or congenital limb deficiency patients.

3 Definitions

Prosthesis: an artificial device that emulates a missing body part, this may be though amputation or congenital limb deficiency. Regarding this policy the hand or part of the hand is being considered.

Myoelectric prosthesis: prosthesis controlled by the recognition and amplification of muscle activity via an external sensor applied to the skin overlying the chosen muscle. Movement is powered by electrical motors.

Single grip prosthetic hand: a prosthetic hand mechanism that simply opens in one axis of rotation having only one motion possible. There is no independently moving digits, 2 finger (index and middle) move in unison, ring and little fingers are passive. Thumb moves in one axis in coordination with the fingers. This allows only 1 grip pattern. This includes full hand and trans- carpal single grip prosthetic hands.

Multi grip prosthetic hand: a prosthetic hand mechanism that allows multiple grip patterns through multiple articulations and controlled and coordinated patterns of

movement. There are 4 current models outlined below referring to number of articulating digits and thumb control.

Multi Grip Powered Digits: a prosthetics device composed of articulating digits that can be created to emulate any or all the fingers or the thumb. This allows multiple grips when combined and considered with the remaining digits for partial hand amputees or congenital absence.

Trans-carpal prosthesis: single grip prosthesis for complete trans-carpal (partial hand) amputee with no remaining fingers or thumb.

X-finger prosthetics: multi-articulating and thus allowing multi grip body powered device specifically designed to replace missing digits. It is an option for patients who have amputations of the fingers at the level of the mid proximal phalanx.

Myoelectric training: carried out by a specialist occupational therapist in amputee rehabilitation via attaching (with medical tape / adhesive) sensors to the skin to first locate the muscles in the forearm or upper arm to which the patient has the best control allowing the sensors to pick up the contractions most efficiently. Following this the patient is trained to control the muscles independently and control the movements with a computer simulator and a prosthetic hand attached to desktop simulator.

Outcome measures: function is relative to the individual patient and the aim is to provide the prosthesis that allows the highest level of function.

4 Aims and Objectives

This aims and objectives of this policy are to set out the NHS England Commissioning position for multi-grip upper limb prosthetics.

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5 Epidemiology and Needs Assessment

The 2010 – 2011 limbless statistics showed the total number of upper limb referrals was 349 patients. 26 patients were referred but did not have an amputation thus the total number of patients in England in that calendar year was 323. Of these there were a maximum of 187 new patients that might have benefitted from multi grip hands, 48 patients who might have benefited from multi grip powered digit prosthetics and 88 patients that might have benefited from the x finger.

As the limbless level rises from partial hand to forequarter, the weight of the prosthesis becomes prohibitive to use also there are patients who are unable to utilise a myoelectric thus is it not anticipated that all will go on to use the myoelectric prosthesis.

6 Evidence Base

NHS England considered the available clinical evidence as described by the Clinical Reference Group. NHS England concluded that there was not sufficient evidence to support the routine commissioning of this treatment for the indication. In the interests of transparency the clinical case that was put to NHS England by the CRG is described below.

> In evaluating myoelectric upper limb with body-powered prostheses, passive prostheses, or no prosthesis prostheses, the most informative data are prospective comparative studies with objective and subjective measures that directly address function and health-related quality of life.
>
> A systematic review of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment. For paediatric patients the mean rejection rate was 38% for passive prostheses (1 study), 45% for body-powered prostheses (3 studies), and 32% for myoelectric prostheses (12 studies). For adults there was considerable variation between studies, with mean rejection rates of 39% (6 studies), 26% (8 studies), and 23% (10 studies) for passive, body-powered and myoelectric prostheses, respectively. The authors found no evidence that the acceptability of passive

prostheses had declined over the period from 1983 to 2004, “despite the advent of myoelectric devices with functional as well as cosmetic appeal.” Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently rejected (80%–87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

In comparative studies of prostheses, subjects served as their own control. Since these studies included use by all subjects of both a myoelectric and a body-powered prosthesis, randomization was directed at the order in which each amputee used the prostheses. Two trials were found in which a total of 196 children used both a myoelectric and a body-powered hand prosthesis, in randomized order, for a period of 3 months each. No clinically relevant objective or subjective difference was found between the two types of prostheses.

A number of small non-randomized case series (n< 50 patients) and online or mailed surveys were found, but few studies directly addressed whether myoelectric prostheses improved function and health-related quality of life. Most of the studies identified described amputees’ self-selected use or rejection rates. The results were usually presented as hours worn at work or school, hours worn at home, and hours worn in social situations. Amputees’ self-reported reasons for use and abandonment were also frequently reported. The limited evidence available suggests that, in comparison with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work, but may have reduced performance under heavy working conditions. The literature also indicated that the percentage of amputees who accepted use of a myoelectric prosthesis

was about the same as those who prefer to use a body-powered prosthesis, and that self-selected use depended at least in part on the individual's activities of daily living. Appearance was most frequently cited as an advantage of myoelectric prostheses. Non use of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Due to the lack of peer-reviewed publications evaluating the functional outcomes of individual digit control in amputees, myoelectric hand prostheses with individual control of digits are considered investigational. There is very little research comparing multi -function prosthetic hands with either body powered prosthetics or single grip prosthetics. However although the research is weak it strongly supports the clinical pathway treating all patients as individuals. The importance of the clinical pathway is ever more important for the patient to be provided with the prosthesis that enables and rehabilitates that individual to allow the highest level of independence possible.

There are no issues with safety and all the limbs come with a full manufacturer's warranty up to 5 years.

7 Rationale behind the Policy Statement

Multi-grip Upper Limb Prosthetics has been considered by NHS England who concluded that there was not sufficient evidence to support the routine commissioning of this treatment.

8 Criteria for Commissioning

NHS England does not routinely commission multi-grip upper limb prosthetics.

9 Patient Pathway

Not applicable.

10 Governance Arrangements

Not applicable.

11 Mechanism for Funding

NHS England will not routinely fund multi-grip upper limb prosthetics for patients with upper limb loss.

12 Audit Requirements

Not applicable

13 Documents which have informed this Policy

Not applicable

14 Links to other Policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

15 Date of Review

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

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