Clinical Commissioning Policy: Provision of multi-grip upper limb prosthetics

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Policy Statement

NHS England will routinely commission multi-articulating 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.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given 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 in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Summary of treatment

Patients with the above conditions 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 on the other shoulder that is 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.

Summary of prevalence

The 2010 – 2011 limbless statistics demonstrated a 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. This divides into 187 patients with a through wrist amputation or above that might benefit from multi-articulating hand prosthesis and 48 patients who might have benefitted from multi-articulating partial hand prosthesis.

Summary of commissioning position

Provision of Multi-articulating hands should be commissioned and provided by the NHS England. The provision should be based on the individual patients needs and a thorough assessment by a skilled multidisciplinary team including a Consultant in Rehabilitation Medicine, Specialist Occupational Therapist in amputee Rehabilitation and Specialist upper limb Prosthetist. The assessment will include a minimum of 12-week period before decision on prosthesis is made.

This document provides the rationale, explanation and clinical pathway for this provision to ensure appropriate it is based on the patient's ability, clinical team experience and cost effectiveness.

1. 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[1]. It has been well recognised that upper limb prosthetic users should be supplied with both functional prostheses, i.e. body powered and myoelectric[2] if they are able to control the prosthetics. Abandonment of prosthetics is lower with myoelectric compared to body powered[3] 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 mult-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.

The aim of this policy is to establish the place of these devices in commissioning guidelines given that there are no significant papers comparing new to old technology. What can be compared is the costs, functional capabilities, training capabilities and warranties.

It is recognised that at the centre of this process is the patient and their need to be viewed and assessed as an individual[4] relating to their abilities and functional needs supported by an appropriate MDT in a Tertiary Centre[5,6] (or standard centre if appropriate experience can be demonstrated).

2. 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.

- I limb 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.
- Unilateral and bilateral: Unilateral refers to one upper limb being affected and bilateral refers to both upper limbs being affected.

	Grip size	Contralateral limb affected	No. of grips	Ability to personalise	Hand Gestures	Act real	Personalised training / programmable
Body powered	Reduced	Yes	1	No	No	No	No
Single grip myoelectric	Reduced	No	1	No	No	No	No
Multi grip passive thumb	Full	No	5-12	Yes	Yes	Yes	No
Multigrip active thumb	Full	No	7-24	Yes	Yes	Yes	I Limb Revolution only
Single grip transcarpal myoelectric	Reduced	No	1	No	No		No
Multi grip – I Limb Digits	Full	No	24	Yes	Yes		Yes

- 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. Assessment of function in upper limb amputees is measured by the following tools:

Type of outcome measure	Subjective	Objective
Disabilities of the Arm, Shoulder and Hand (DASH)	✔	
Southampton Hand Assessment Profile (SHAPS)		✔
Trinity Amputation and Prosthesis Experience Scales; assesses the adjustment to amputation and a prosthesis and provides a satisfaction measure of the prosthesis (TAPES)	✔	
Box and Blocks; a timed and repeatable test measured the duration to construct and deconstruct a tower using wooden building blocks.		✔
9 hole peg test; a timed and repeatable test measuring the duration to place 9 wooden pegs into holes and remove them.		✔
Canadian Occupational Performance Measures (COPM)	✔	✔

3. Aim and objectives

This policy aims to :

- Outline the policy for provision of multi grip hands (and thus single grip hands by default) and I limb digits and to demonstrate the clinical pathway to allow appropriate use of funds, in order to maximise function of patients with upper limb amputations or congenital limb deficiency.
- Demonstrate the methodology of the pathway and it's application thereof.
- To tie in provision of multi grip hands and I limb digits with the national service spec.

The objectives are to:

- Outline the current provision nationally
- Outline products currently available on the market and recent developments in upper limb prosthetics
- Elucidate the position of the new technology in the provision of upper limb

prosthetics nationally

- Outline the method of auditing limb provision to ensure this policy can be reviewed with better data than is currently available.
- Outline the service specification for centres providing multi grip hands.

4. Epidemiology and needs assessment

The function of the upper limb is to position the hand in time and space to act on an object. This may be to create an opposing force such as to push open a door, to grip an object in a firm manner such as a tin of beans, in a soft manner such as a glass or polystyrene cup with the hand conforming with 5 digits to the shape of the receptacle, delicate manner such as a key between the thumb and to index finger, to point or press with an individual finger such as typing, to communicate such as hand gestures. When assessing these attributes the position of the hand is essential for smooth function and loss of function in one limb leads to overuse injuries such as tenosynovitis in the other limb[7]. To grip and take hold of an object is a complex process, there are 12 defined grips that accommodate different shapes and process. There are numerous hand gestures such as the OK sign, thumbs up, 'hand loose' and 'let's go bowling' gestures that are taken for granted that can be programmed in and be used to assist in communication.

Alternatives for upper limb prosthetics can be considered thus:

- Cosmetic hands have no intrinsic active moving parts, the digits are positioned but act as passive shape. The hands can be used to apply force such as pushing or pulling or to hold a glass against gravity, but there is no active control.
- Body powered prosthetic hands are attached by a cord and shoulder harness to the contralateral shoulder, when this is moved forward and the cord pulled the hand will open in a linear manner, there is only 1 grip, the hand opens and closes. The hand does not conform to the object, has 2 or 3 points of contact and has a manual wrist. The x finger is body powered but relies on a hand mount.
- Single grip myoelectric hands do not involve the contralateral limb for control (unless it is used for elbow control in amputations or deficiencies above the elbow) but the hand has the same limitations in grip, the hand opens and closes in a linear manner and there is 2 or 3 points of contact. This makes it harder and not reliable for holding objects such as drinking receptacles, tools etc. the cosmetic effect is a thickened hand and the linear movement of the opening and closing draws attention.
- Multi grip hands with manual thumb (abduction and adduction) allow up to 14 pre-programmed grip / gesture patterns. The positioning and ability of multi-grip hands allows simpler and more effective ability to grip objects if the hand is in the correct mode.
- Multi grip hands with powered thumb (abduction and adduction) allowing the thumb to automatically assume the correct position for the specific grip selected. Thus less thought required by the patient, less movement of the contralateral limb to position the thumb in the correct position. The grip patterns are up to 24 in this category. This improves the speed of attaining the

correct grip.

Incidence and prevalence:

The 2010 – 2011 limbless statistics are outlined below, 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.

Current demand:

Thus in 2010-2011 (see table A) there were a maximum of 187 new patients that might have benefitted from multi-grip hands and 48 patients who might have benefited from I limb digits prosthetics. (Due to the bulk of the prosthesis, I limb digits is not suitable for individual finger loss up to the knuckle unless a partial hand amputation is carried out, hence digits not included) 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.

It should be noted that patients with bilateral upper limb amputations (4 in 2010-2011 and included in the figures above) have a usual prescription of one myoelectric prosthesis and one body powered prosthesis, or 2 body powered prostheses. This is due to the increased weight of the myoelectric prosthesis over the body powered prosthesis. (There are no published papers on this subject)

Audit of current myoelectric provision in UK:

The aim of the audit was to assess the current level of provision of the myoelectric prosthetics in terms of number of upper limb patients, number of those using myoelectic hands both in terms of single grip and multi grip.

16 out of the 45 centres responded, but this did include the largest centres in the UK such as Belfast, Birmingham, Glasgow and Manchester.

Estimated current cost (single grip hand average 5 year costs of £5,750)	£2,650,750	Extra 5 yr costs	Expected yearly increase in funding required
Estimated minimum maximum 5 Year total cost (i.e. most expensive scenario of current users if all patients with current single grip myoelectrics were	£8,666,800	**£6,016,050**	**£1,203,210**

upgraded to I limb revolution)			
Estimated maximum maximum cost. (i.e. most expensive scenario of current users if all current single grip myoelectric users upgraded to Michaelangelo)	£15,674,000	£13,023,250	£2,604,650

It is also clear from the stats returned from the centres who were cooperative in the audit that only about 7-8% of upper limb amputees become myoelectric users. Thus the figures above concern existing users as the number of new users of myoelectric prosthetics will be small. It does however remain to be seen how the increased functionality of the multi-grip hand might change this. It should be noted that currently there is no available evidence on the long term use of the multigrip hands however with the added functionality it is likely to be much higher.

Predicted costs for options of adopting Multi-grip hand protocol.

Thus **increase** in funding **of up to £6 million** for protocol **including up to I limb Revolution.**

or

Thus **increase** in funding **of up to £13 million** for protocol **including Michaelangelo.**

(For I limb digits x – finger a more in-depth study will be required)

For new patients (187) that might be suitable for I limb it would be a maximum of £3.5 million to include protocol up to I limb revolution or £6.4 Million to go up to the Michaelangelo. However as demonstrated by the national figures above the number of amputees that actually use myoelectics would be much smaller than that.

For Partial hand prosthetics a more in-depth study is required but per patient the maximum would be £18406, as 44 patients – yearly cost – £0.8 million per year (warranty 3 years)

For x finger - £10350, as 88 patients – yearly cost for new patients - £0.9 million per year (warranty 1 yr)

It is very difficult to assess updating existing partial hand and digit amputees as most do not use prosthetics.

5. Evidence base

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 summary of evidence from relevant studies is presented below [11].

i. Efficacy

Amputation at wrist or above

Systematic review

A systematic review of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment[12]. For pediatric 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.

Randomized Controlled Trials

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[13,14]. No clinically relevant objective or subjective difference was found between the two types of prostheses.

Non-randomised trials

A number of small non-randomized case series (n< 50 patients) [15,16,17] and online or mailed surveys [3,10,18,19] 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. Nonuse of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Amputation below wrist (Hand or Digits)

No peer-reviewed publications were found to evaluate functional outcomes of individual digit control in amputees.

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.

ii. Safety – there are no issues with safety and all the limbs come with a full manufacturers warranty up to 5 years. (The I limb includes accidental damage also)

iii. Impact on quality of life, very little research has been carried out on multigrip hands.

a. Myoelectric users wear their prosthetics for an average of 8 hours a day[10].
b. Activities for which prostheses should be useful include: handicrafts, personal hygiene, using cutlery, operation of electronic and domestic devices and dressing and undressing[10].
c. Touch Bionics have been carrying out assessments as part of their provision. They have demonstrated so far an improvement in DASH of from 33.98 to 27.39 with a P value of 0.019 and a case load of 37 patients. This has not been published yet but has been presented at an international conference. (ISPO 2013 Hyderabad)
d. Otr et al[9] (2010) published a case report comparing a early Multi grip I-limb prosthetic hand with a single grip hand. In their conclusions they suggested that the patient preferred the multi grip hand demonstrated by TAPES and advised that the patient should be trialled and the outcome decide the prescription which supports the clinical pathway presented here.
e. A university of Manchester[11] project demonstrated improved outcomes with the use of a Multi grip I-limb prosthetic hand and decreased shoulder

movement compared to using a single grip body powered prosthesis.

f. There is little research but these are the words of a multi grip prosthetic hand user.

'I am a former Royal Marines Commando and double amputee.

I am still learning but getting quickly used to the new technologies in this hand, which I am very privileged to have. There are many benefits to using this hand, all of which help me in different circumstances. For instance I have the option of twenty- four grip patterns, a motorised thumb and an app (application) on my phone to set my preferences.

The app I find is the best quality in this hand, I have the freedom to set the hand as I wish to use it. This means if I want to change anything I haven't to travel or make appointments just to adapt the grip patterns. I set the grips, which I need at anytime and choose which I will use for different environments.

Also on the app is a real-time graph and this helps with training my muscles to best use the sensors in the prosthesis, I can see as I use the arm if I am activating the sensors correctly and also when my muscles are begging to fatigue.

This hand covers all needs I require from upper limb prosthesis, it doesn't try to look too real, it acts real which I find much more important and is as practical as can be without having my arm back. I feel much more confident having this as I can fill shirts when meeting clients, not worry about carrying objects and have purpose again through not asking for help carrying out activities. '

iv. Cost-effectiveness

There are published cost-effectiveness studies however a financial impact analysis is presented below.

a. The breakdown of the tariff on table D outlines the expected 5 year costs. The assumption is based on the all the products having a 2 year warranty except the I-limb (both models come with 5 year warranty). Table E outlines the options for the multi grip prosthetics for finger and partial hand amputees.
b. The tariff also outlines the cost of the replacement gloves which is usually 3 / year. (Note the I-limb package comes with free gloves provided outcome measures are returned regularly to the manufacturers)
c. Independent training and setting up of new grips can be achieved with the Be-bionic and I-limb range. The use of interactive smartphone and tablet apps in the latter make this simple and easy to operate.
d. The multi-grip hands can be programmed to perform just 1 grip to emulate the single grip hands.
e. The significant factors are outlined below in table C below
f. Warranty: different manufacturers offer different warranties, these are outlined above.

i. It is of significance that the I-limb has 5 years warranty including accidental damage. This is the only warranty that covers accidental damage. This significantly improves the cost effectiveness.

g. Warranty varies between products, this should be taken into account as it might affect future costs incurred to the centre
   i. Manufacturers warranty – fault only
   ii. Accidental damage cover – accidental damage such as trapping the unit in a car door.

h. The multi grip hands can be programmed to have just 1 grip and then 2 etc to embellish training after provision.

i. Single grip hands are more robust and more suited to heavy manual use.

Summary of cost analysis

	Total	**Increased funding required**	
		Total increase required for next 5 years	**Average yearly cost**
Maximum cost for updating all current myo hand users with protocol including up to I limb revolution (not including the michaelangelo hand). (ie Existing users enter protocol when current prosthesis needs replacing)	£8,666,800	**£6,016,050**	**£1,203,210**
Maximum cost for updating all current myo hand users with protocol including up to michaelangelo. (ie Existing users enter protocol when current prosthesis needs replacing)	£15,674,000	**£13,023,250**	**£2,604,650**
New patients only – i-limb digits **Yearly cost (maximum)**	£810,000		**£810,000**
New patients only – x finger **Yearly cost (maximum)**	£911,000		**£911,000**

These costs are the theoretical maximum extra costs (considering £2,650,750 currently spent nationally) of upgrading existing users to the maximum prescription

of the I limb revolution (£6,016,050 over 5 years or £1,203,210 per year) (prescription not including michaelangelo) or alternatively including Michelangelo (£13,023,250 over 5 years or £2,604,650).

This does not take into account previous users who have abandoned the use of the myo-electric prosthesis in the past. However the provision of the prosthesis should be based on the clinical pathway and being able to demonstrate satisfactory outcome measures in parallel with patients subjective account and MDT report. Thus the provision should be not be based on desire and cosmetics alone but must have functional outcome improvement at its core.

6. Rationale behind the policy statement

The purpose of this document is to secure multi grip and thus multifunctional upper limb prostheses as **part** of the basket of prosthetic solutions offered to patients. It is not to suggest that multi grip upper limb prostheses are the only type of prosthesis considered. A patient should be assessed by a specialist upper limb deficiency team, including a Consultant, Occupational Therapist and a Prosthetist. The team will assess using the suggested patient pathway; this pathway will allow the team to assess the physical manipulation, psychological and social needs of the patient. It is very important that the patient is kept informed and consulted at all levels of discussion making. In this way the most clinically and cost effective prosthetic provision can be chosen. This could be a body powered, single grip myoelectric or multi grip / multifunctional myoelectric upper limb prosthesis.

When the clinical and cost effectiveness of a prosthetic provision is being considered the whole of the person must be considered; as well as the different functions that a hand has.

For example, a hand is not only a tool for holding things, it communicates and interacts with others, it completes our body image, it makes a statement about the who we are.

Body powered split hook prostheses fulfil some of the functions of a natural hand. They give good holding function in one plane. Allowing for two flat surfaces to pinch together to hold an object and make hold on the first point of contact. The pinch allows for the holding of objects such as a pin or book, if the object has a curved surface such as a can or a mug the object is difficult to grasp as it slips away from the hinged scissor grip. Flexible, or fragile objects such as plastic cups or glasses are vulnerable to being crushed. They have a no cosmetic function this can cause social and psychological rejection. This type of prosthesis is however very robust.

Body powered mechanical hand prosthesis allow for a limited chuck grip, the ability to hold an object such as an eggcup. It has some cosmetic effect.

Single grip myoelectric prosthesis offers a chuck grip, the index and middle finger pads closing onto the thumb pad. This allows for the holding of an object such as cylindrical mug or a piece of paper can be put into the prosthesis it is not possible to pick up paper, or a similar thin object, directly from a table. The chuck grip offers a pinch on a single access; this means that if holding an object the pinch can act as a pivot as the grip is between to points. As the chuck pinch is in a single plane it requires compensation movements in the rest of the arm, and sometimes the whole

body, in order to pick up an object. Due to the gross nature of the chuck grip it is not always possible to pick something up directly, an object has to be places in the prosthesis by the other natural hand. Thus occupying the natural hand during an activity, making the activity longer and unnatural in execution. The prostheses are robust in taking knocks and weights. This type of prosthesis is more cosmetic than the body powered prostheses and can therefore fulfil more or the psychological and social functions of a hand.

Multi grip upper limb prostheses allow between 7 to 24 grip types that the user can choose between. This allows for the picking up, stabilising, and grasp of most objects from picking up a pin to holding a contorted shaped object such as a 'coke cola' bottle as each digit moves into the surface of the object and stops as it touches the surface. The multi point grips allow the prosthesis to stabilise an object rather than creating a pivot. Interestingly a proficient user (JL) of such a prostheses reported that he rarely uses the chuck grip option, this being the only grip offered by the single axis myoelectric. Due to the variety of grips compensation movements by the rest of the body are greatly reduced. The variety of grips allows for direct picking up of small objects so the other hand does not have to pick it up and hand it over. Thus the hands are independent of each other, making the execution of an activity more efficient and naturalistic.

The long term effects of compensatory movements, or over use of other parts of the body have not been proven as longitudinal studies have not had time to be completed. However it is possible to make a clinical judgement that these compensation and over use movements will cause bio-mechanical problems in the future for these patients.

The prosthesis can also make hand gestures, such a 'thumbs up' or 'okay' sign; it is possible to shake hands as the prosthesis conforms to the hand of the other. These social interactions offer a wider scope of the functions of a hand. Communicating interacting and touching others in this way has an important psychological and social functioning of the limb deficient person. The fluidity and elegance of the movement of all the fingers of the multi-articulating prosthesis gives it a further dimension of naturalness. Cosmesis is not static, can about the nature of movement. A patient reported that the 'honesty of the robotic look' of the prosthesis added to its cosmesis. The psychological and social impact of the prosthesis can add an element to rehabilitation and enablement that the other types of prosthetics cannot.

The multi-articulating prostheses are reasonably robust, but are not recommended for in vigorous activities such as mountain biking.

Research has shown that the time between readiness for prosthetic provision, and actual prosthetic provision has an impact on the patient's ability to integrate the prosthesis into daily activities, as well as good training. Delay in provision can be detrimental if specialist funding has to be applied for when a clinical and cost effectiveness assessment has to be made before provision. If the prescription guidelines allow for the provision of the correct prosthesis this delay can be minimised. The immediate provision of the correct prosthesis can also reduce duplication of provision. For example, a patient being provided with one type of prosthesis as an intermediate stage while waiting for provision of another.

The provision of the correct prosthesis, considering its physical, psychological and social function allows the patient to accept the loss of a limb/s. This acceptance enables the patient to return to their roles within a family, work and social world more efficiently. Acceptance of limb deficiency and integration of a prosthesis into daily life allows a greater level of normality, and a reduction in the use of medical resources.

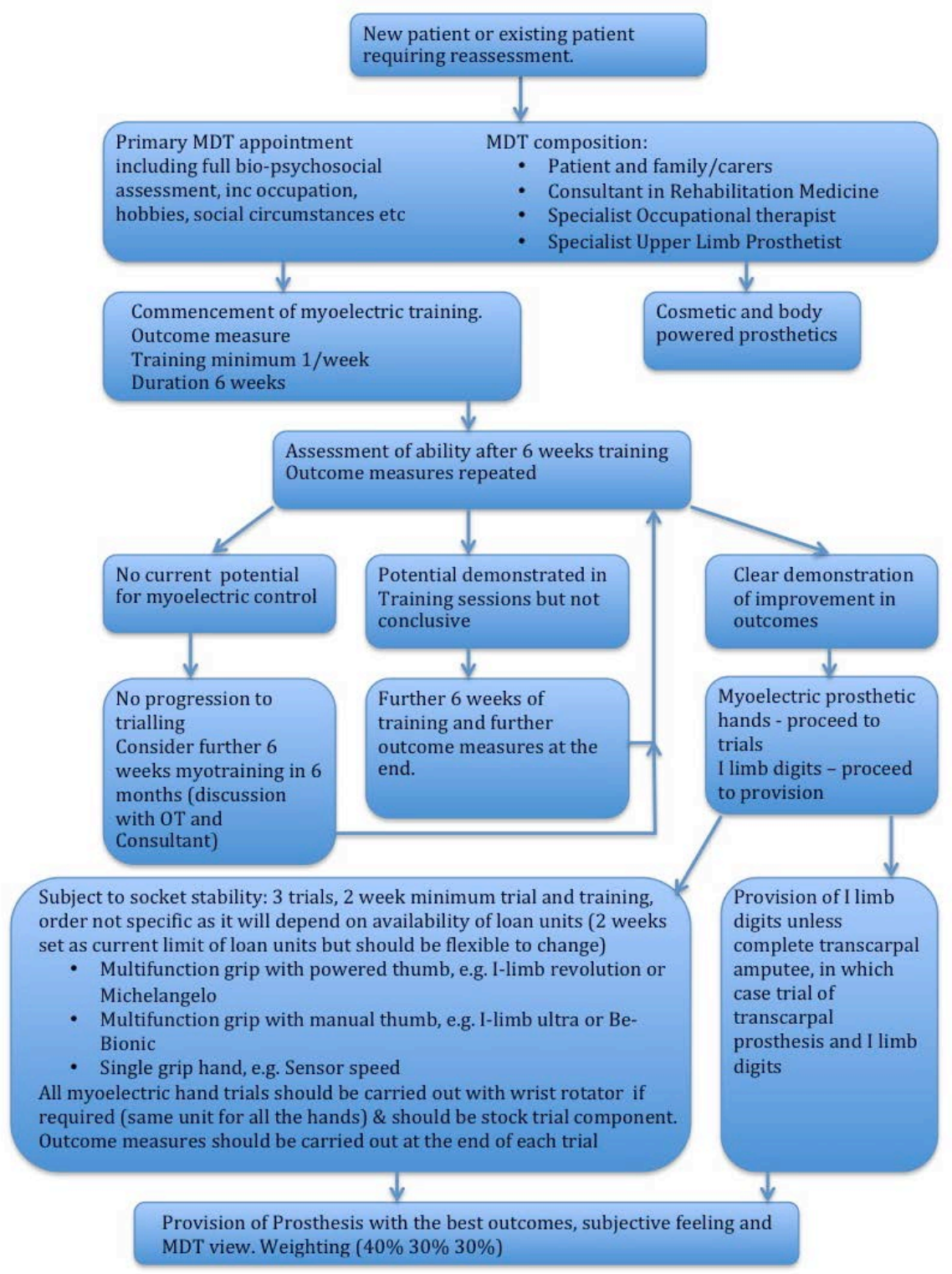
7. Criteria for commissioning

- Indications for provision should be based on:
    - Individual patient training and subsequent assessment of function demonstrating both subjective and objective evidence of improved function and outcome with the multi-grip opposed to the single grip hand.
    - Improvement in appropriate outcome measures (see definitions)
    - Appropriate goal setting
- Inclusion critera:
    - Adult, child, unilateral, bilateral, all amputations levels should be included and considered equally in the provision of training and assessment for multi grip myoelectric hands. It is recognised that the multi grip hands and digits are predominantly adult or adolescent sizes currently but this policy aims to cover future production of smaller child appropriate multi grip hands and digits.
    - Any age, sex, race or amputation level (if appropriate for prosthetics).
- Exclusions from the patient pathway
    - If it is felt by the consultant that the patient will not look after the unit in an appropriate manner or could put others at risk (i.e. history of recurrent damage to prosthesis)
    - Patient already has a multi grip prosthesis provided and there is no change in prosthetic development or patients condition
- Location of provision
    - At a Tertiary centre or Standard centre if appropriately trained and experienced staff present
    - Appropriate and separate paediatric and adult upper limb treatment rooms
- Contra indications
    - Assessment does not demonstrate improved function with multi grip hand either in training or in trial.
- Training and assessment criteria
    - Should be as soon as the patient and consultant have discussed and agreed on the commencement of the training.
    - Cessation to training should be if it there is clear non progression in outcome measures or development. It is recognised that each patient is unique and this needs to be discussed with between the Patient, Occupational Therapist and Consultant in Rehabilitation, who will have the overall responsibility to make the decision to halt the assessment process. However this can be restarted by the Consultant after a suitable passage of time to be decided between the Consultant and

the patient, it would be expected that this would be no sooner than 6 months hence.
    - Cessation of provision should be if the patient does not use the prosthesis on a regular basis (it can be serviced and provided to another patient). The use of the prosthesis will be assessed on regular review appointments with the Consultant, Occupational Therapist or Prosthetist with appropriate outcome measures being done on a regular basis, in order to carry out audit and demonstrate level of effectiveness on a national basis.
    - Repeat outcome measures should be performed at 6 monthly intervals to assist in audit and review.
    - Ability of the prosthesis to assist in training and for the patient to be able to control the functionality and adapt the grips independently.
- Requirements of providing centre
    - Multidisciplinary team experience with multi grip hands (this may necessitate training by companies or other more experienced NHS centres)

Tertiary centres based on the national service specification

8. Patient pathway



The patient pathway has been developed because the level of technology has moved swiftly in the last few years but funding has not changed with this pace. The result has been that the technology has been adopted in some centres but not by most (see page 13).

The pathway treats patients as individuals with different lives, hobbies, hopes and aspirations, they also have different levels of ability to use the different prosthesis and have differing priorities in what they want out from an artificial limb. Patients must be treated as individuals and they must be assessed as individuals. Thus the provision of any type of upper limb prosthesis should be based on the function, outcome measures (see definitions) and subjective assessment by the patient and MDT.

The aim of the pathway is to be patient centred, to focus the assessment and the progress down the pathway based on the 3 factors.

1. The subjective patients views
2. The knowledge and experience of the MDT
3. The outcome measures using both subjective and objective outcome tools

The method is also to provide the patient with the best prosthesis for the patient via a thorough assessment. It is recognised that not all the different types of prosthetics can be trialled and to this end the various myoelectric prosthetics have been categorised in to three groups which will be triaged with appropriate outcome measures. The decision will be then be made by the Consultant who will prescribe based on the above 3 factors namely the best outcome measures, the patients subjective account of preferred prosthesis and the MDT's recommendation. The three categories are below and the representative unit from each category would be chosen by the patient and MDT.

1. Single Grip prosthesis: examples such as; RSL steeper myoelectric, Twin digital, DMC plus, variplus and sensor speed .
2. Multi grip hand with manual thumb: Be Bionic and I Limb Ultra
3. Multi grip hand with powered thumb: Michelangelo and I Limb Revolution

For partial hand and finger prosthetics there are three options

1. Single grip Transcarpal prosthesis: only suitable for complete transcarpal amputees (all fingers and thumb)
2. Multi grip - I limb digits: suitable for digit loss and partial hand amputees allowing multiple grips as will oppose remaining digits.
3. X finger prosthetics: suitable for finger amputations at the proximal phalanx level.

It is essential that all patients have a thorough assessment via the pathway including patients who have previously had myoelectric single grip prosthetics supplied but who have abandoned the use of a myoelectric prosthetics. Demonstrating significant functional improvement via outcome measures will be essential in this group given the history of abandonment.

9. Governance arrangements

- Service specification for provision of multi grip hands
    - Tertiary centre

        - Consultant in amputee rehabilitation
        - Specialist Occupational Therapist in Amputee Rehabilitation
        - Dedicated Upper Limb Prosthetist
        - Treatment of Children, adults, complex and multiple limb loss
- Auditing and monitoring
    - Subgroup to continue and receive all outcome measures for national database and reporting back in 1 year to National CRG to demonstrate outcomes of Prescription policy and as a result recommendations for policy revision.
    - Report of all upper limb patients assessed for myoelectric should be collated to the group.
    - Assessment of outcome should be on-going. (6 monthly outcome measures to be collated by the subcommittee).
    - Subcommittee should meet annually to reassess the developments in prosthetics and audit outcomes to lead to recommendations for policy revision to CRG annually. (e.g. routine review of new prosthetics and developments such as targeted muscle re-innervation)
    - If significant change in prosthetic development or audit results then the subcommittee may be recalled by any of it's members. (E.g. new prosthesis on the market, prosthesis failure / recall, significant unexpected audit findings)

10. Mechanism for funding

Activity (outpatient appointments, trials and maintenance) is funded through the contracts held by NHS England at the agreed tariff price. Limb costs are funded on a cost per case basis.

See table D E for all the costs.

11. Audit requirements

- Subgroup to continue and receive all outcome measures for national database and reporting back in 1 year to National CRG to demonstrate outcomes of Prescription policy and as a result recommendations for policy revision.
- Report of all upper limb patients assessed for myoelectric should be collated to the group.
- Assessment of outcome should be on going. (6 monthly outcome measures to be collated by the subcommittee).
- Subcommittee should meet annually to reassess the developments in prosthetics and audit outcomes to lead to recommendations for policy revision to CRG annually. (e.g. routine review of new prosthetics and

developments such as targeted muscle re-innervation)

- If significant change in prosthetic development or audit results then the subcommittee may be recalled by any of its members. (E.g. new prosthesis on the market, prosthesis failure / recall, significant unexpected audit findings)

12. Documents which have informed this policy

- Commissioning for Patients: Guidelines for National Commissioning of Specialized Services for Patients of All ages with limb loss. (DOH Document) 2011.
- National Service Specification for Amputee Rehabilitation.
- National Service Framework for long-term conditions (2005)
- Dr Andrew Murrison MD, MP 'A Better Deal for Military Amputees', 2011
- Department of Health (2010), Equity and excellence: Liberating the NHS: section 3 Putting the patients and the public first, Department of Health, London
- Audit Commission (2000), Fully equipped; The provision of equipment to older or disabled people by the NHS and social services in England and Wales, London http://archive.auditcommission.
- gov.uk/auditcommission/nationalstudies/health/socialcare/pages/fullyequipped.aspx.html
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- Audit Commission (2004), Guidance on the commissioning of prosthetics services, London, http://archive.auditcommission.gov.uk/auditcommission/SiteCollectionDocuments/AuditCommissionReports/NationalStudies/olderpeopleprosthetics.pdf
- NICE Guidelines: Promoting Physical Activity for Children and Young People (Jan 2009)

Multi-Disciplinary Team

- British Society of Rehabilitation Medicine (2003), Amputee and Prosthetic Rehabilitation –standards and guidelines (2nd edition) section 4.19, British Society of Rehabilitation Medicine, London
- National Prosthetic Centre Managers Group (2010), National Service Specification for Prosthetic and Amputee Rehabilitation Services, National

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- Royal College of Physicians & British Society of Rehabilitation Medicine (2010), Medical rehabilitation in 2011 and beyond. A report of a working party (6.21), London
- British Association of Prosthetists and Orthotists (2005), Guidelines for best practice No 1: The Role of the Prosthetist/Orthotist (Issued 2000 and then re-issued in February 2005, British Association of Prosthetists and Orthotists, Paisley
- Upper limb Prosthetic Rehabilitation – Guidance document. College of Occupational Therapists (2006) College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB

13. Links to other policies

- National Service Specification: Complex Disability Equipment-Prosthetic Specialised Services for People of All Ages with Limb Loss
- CQUINs for Amputee Rehabilitation/Prosthetics
- National Service Framework for long-term conditions (2005)

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).

14. 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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