

Clinical Commissioning Policy

Multi-grip prosthetic hand (all ages) (2009) [220801P]

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Commissioning position

Summary

The policy is that the multi-grip myoelectric control prosthetic hand is recommended to be available as a routine commissioning treatment option for congenital upper limb deficiency or upper limb amputation within the criteria set out in this document.

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.

Executive summary

This policy is focused on congenital upper limb deficiency or upper limb amputation (unilateral or bilateral limb absence) and the use of a myoelectric control multi-grip prosthetic for hand, digit or partial hand absence. A multi-grip hand prosthetic is a device which emulates a missing body part and provides more than a single grip pattern. A multi-grip prosthetic can be powered either through myo-electric (an external power source) or body powered (using remaining digit(s), hand or opposite limb control).

An independent evidence review found there was no evidence for non-myoelectric control multi-grip prosthetics. The evidence base for myoelectric control multi-grip prosthetics, is presented within this policy for a routine commissioning position.

Plain language summary

Congenital upper limb deficiency and upper limb amputation

Patients with upper limb (arm, hand or finger(s)) absence, either as a result of amputation (loss which could be the result of surgery or trauma) or congenital (birth) deficiency are routinely offered rehabilitation (support and training to adapt to a missing body part). A prosthetic is a device that reproduces the function of the missing body part and it facilitates enablement (ways to promote doing activities) to improve an individual's function and independence.

Current prosthetic provision

Currently in the NHS, prosthetic hands are either:

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- **Body powered**-meaning they are controlled by the remaining muscles or the opposite side using a pulley mechanism or connecting joints in the device. This type of prosthetic can have a hook or hand which provides the grip. The prosthetic can open and close in one direction (a single grip) or are designed with mechanisms which allow the user more than one grip pattern (a multi-grip device).
- **Passive functional prosthetics**-which have been known in the past as a cosmetic or replica hand. This prosthetic has no moving parts, but can help the user with the appearance of limb loss. The passive functional prosthetic can also help with non-grasping tasks, such as pushing and pulling objects or holding something steady while the opposite side performs a task. The new term reflects the prosthetic has a greater role than just replacing the hand in appearance.
- **Single grip myoelectric control prosthetics**-a prosthetic, which is controlled by a battery source, but it will only open and close in one direction (a single grip).

The prosthetics above can also be individually designed with a specific task in mind, known as an **activity based terminal device**. The prosthetic is adapted for user need and the prosthetic can incorporate a piece of equipment, a tool or a utensil. An example of an activity based terminal device would be a prosthetic which has a spoon utensil to allow the individual to feed themselves.

Each prosthetic has positive and negative points, as none can replace the full function of the hand. Some individuals with upper limb absence may also choose not to use a prosthetic.

Providing a prosthetic is only one part of rehabilitation. The user needs to be assessed, trained and supported with an appropriate prosthetic by trained team members, who are part of a multi-disciplinary team (MDT). The MDT means that the team members have different areas of skills and expertise and includes doctors, nurses and physiotherapists as well as occupational therapists and prosthetic technicians. The user is at the centre of this process, as each person with limb absence has their own unique needs, goals and outcomes.

Proposed Treatment

A multi-grip prosthetic allows more than one grip pattern. A multi-grip prosthetic can be controlled in two ways, body-powered (using the remaining joint, finger or the muscles on the other side) or myoelectric (powered by a battery source and controlled by learnt specific muscle movements in the remaining arm, hand or finger). As the multi-grip prosthetic has more than one grip pattern, and the myoelectric controlled device is not dependent on the other muscle groups or the opposite side, it can facilitate a greater range of movements making completing tasks easier for the user. The aim of a multi-grip prosthetic is to promote a greater sense of independence and functioning for those with limb absence.

What we have decided

NHS England has carefully reviewed the evidence to treat congenital upper limb deficiency or upper limb amputation with the multi-grip prosthetic hand. We have concluded that there is enough evidence to make the myoelectric control multi-grip prosthetic available and insufficient evidence to support non-myoelectric control multi-grip prosthetics at this time.

Links and updates to other policies

Multi-grip upper limb prosthetics were reviewed by NHS England in 2015, policy D01/P/c. The conclusion was that there was insufficient evidence to support the routine commissioning of this intervention.

This current policy is linked to the Service Specifications D01/S/d for Complex Disability Equipment (all ages) and Service Specifications 1685, Hand and Upper Limb Transplant Service (adults). It is also linked to D01/P/a High Definition Silicone for limb prostheses (all ages).

Committee discussion

See the committee papers (link) for full details of the evidence.

Congenital upper limb deficiency and upper limb amputation

Upper limb absence in adults and children as a result of either an acquired amputation or congenital (birth) deficiency can be unilateral (one side) or bilateral (both sides). The level of absence is referenced to the bone structure underneath.

If limb deficiency occurs at the level of the joint it is called disarticulation (shoulder, elbow or wrist disarticulation). Amputation levels occurring between joints, from proximal (closer to the body) to distal (further away from the body) are:

- forequarter (above the shoulder);
- transhumeral (above the elbow);
- transradial (below the elbow) and
- transcarpal (distal to the wrist).

Transcarpal amputation includes partial hand, thumb and/or 1-5 digit amputation.

Patients with upper limb absence, either as a result of amputation or congenital (birth) deficiency are routinely offered rehabilitation and enablement using a prosthetic, a device that emulates a missing body part (NHS England. 2015). Prosthetic rehabilitation is the clinical practice to use prosthetics and appliances to restore function in people with limb loss (NHS England. 2019). The core objectives of prosthetic rehabilitation are to facilitate the active participation of the individual, achieving the highest functional level possible (NHS England. 2019).

Active participation aims to maximise independence and inclusion in society. Important examples of active participation are to ensure children can participate in educational settings and adults can participate in work and family roles. Prosthetic rehabilitation recognises that the patient is at the centre of this process and needs to be considered as an individual, with individual abilities, functional needs and goals.

Prosthetic provision

Prosthetic choice is dependent on the amputation level, patient factors and importantly functional need. Upper limb prosthetics can be passive (no intrinsic moving parts) or functional. Passive prosthetics aim to provide aesthetic (cosmetic) substitution for the missing body part and to perform non-grasping tasks. Functional prosthetics aim to facilitate tasks that would normally be accomplished by the missing limb.

Functional prosthetics are either body-powered or electrically powered. In electrically powered prosthetics, the device can be activated and controlled by switches or myoelectric control using an Electro MyoGraphy (EMG) signal from residual muscle groups.

Functional prosthetics can be single grip, offering a limited range of motion in which the digits and/or thumb work in unison, or multi-grip, which allows more than one grip pattern. Multi-grip devices allow an independence of thumb and/or digit control (unless the amputation level precludes this).

There are three main groups of hand prosthetics:

1. Body powered devices in which a cord opens the hand in one simple motion when pulled (usually by the shoulder or the opposite shoulder). Body powered digits or partial hand loss prosthetics use the remaining digit or partial hand to operate.
2. Myoelectric control devices are powered by an external power source. Sensors are activated by remaining muscles which control motor(s) to open the hand in either a single, or multiple grippattern.

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3. Passive functional devices (which also includes cosmetic or aesthetic hands). This category includes prosthetic hands which have no intrinsic moving parts. They are used for non-grasping tasks such as stabilising, supporting and pushing/pulling. They also address the cosmetic issues of limb difference.

Activity based devices (specific designed terminal device prosthetics) are based on user need/function which is individually determined. These prosthetics allow the user to complete a key task such as complete an activity of daily living (examples include eating, washing or using a tool) with limb absence. Activity based devices can be customised from the above three main groups of prosthetics.

Prosthetic considerations

Despite the advances in technology over the past years, developments in prosthetics still cannot produce the complexity of the natural hand and each prosthetic group has advantages and limitations for the user.

Body-powered devices are durable, light to wear, simple to operate and do not rely on an external power source. They provide better non-visual cues to the user about the grip of objects and are suitable for heavy duty tasks. The limitations of body-powered devices include the reduced functional movements which can be achieved with the device and the lack of cosmetic effect (particularly with body-powered hook devices) which can have a social and psychological impact.

Single grip prosthetics include body powered and myoelectric control devices. The terminal device can be a hook, hand or partial hand prosthetic. They offer a limited range of movement (open and close) in a single axis using a scissor grip (a pinch mechanism) in the case of a hook device, or a chuck grip (where the thumb, second and middle finger move in unison) in a body-powered or myoelectric hand/partial hand device. Though these terminal devices can hold objects in one plane, curved objects can be difficult to grasp and flexible or fragile objects (such as plastic cups or glasses) are vulnerable to being crushed, particularly in the hinged scissor grip of a prosthetic hook. The single grip means users may struggle to pick up certain objects and need compensatory movements such as manipulation of the object with the other hand to facilitate the grip.

Body powered devices also require a harness and the opposite side or shoulder to operate, meaning the hands are not independent of each other. In body-powered digit or partial hand prosthetics, the prosthesis might be connected to neighbouring fingers and/or remaining hand by a supporting connector. The long-term effects of compensatory movements, or over-use in the surviving / contralateral muscle groups are thought to lead to bio-mechanical imbalance issues in the user.

Limitations of myoelectric prosthetics include the lack of sensory feedback to the user; the weight of the device (which increases if the amputation is more proximal); device responsiveness and user concerns about durability/damage to the device, particularly for heavy tasks. The myoelectric multi-grip device also requires users to learn multiple co-ordinated movements to control the device and grip patterns, which can require significant user concentration and training.

Given their limitations, the choice of the prosthetic needs to be tailored to the individual and their activities.

Current standard prosthetics in NHS England are:

- Body powered prosthetics with either a hook or single grip hand as a terminal device
- Passive functional prosthetics
- Single grip myoelectric control prosthetics

Patients may also choose not to wear a prosthetic.

Proposed treatment with the multi-grip myoelectric control prosthetic

Myoelectric control multi-grip devices allow between 7-24 different grip patterns, allowing the user to stabilise and grasp an object rather than creating a pivot to pick it up. This makes the execution of an activity more efficient and natural, reducing the compensatory mechanisms needed to pick up and manipulate objects. This improved dexterity does not require the opposite side to control, allowing hand independence. Some device models have either a powered or unpowered thumb.

The myoelectric multi-grip device can also facilitate social and communicative interaction, through the grip patterns to make gestures such as “OK” and the “Thumbs Up” sign. In some models, the myoelectric multi-grip functions can be pre-programmed and user adapted, promoting individuality. These functions address the wider non-physical role the hand plays in communicative and social functioning, which are important for participation and the psychological adaption for those with limb difference.

Device provision is only one element of prosthetic enablement. The intervention requires that patients are viewed and assessed as individuals considering their health and well-being as well as their functional needs. Patients should be supported by an appropriately trained multi-disciplinary team (MDT). This team assesses patients for suitability for a prosthetic device and provides their rehabilitation alongside individual training.

Patients will also require ongoing care and support as well as device maintenance, repair/replacement. This ongoing care needs to be adaptive to the individual’s needs and activities, which may change over time.

Epidemiology and needs assessment

The number of patients with an amputation or congenital limb deficiency attending specialist rehabilitation service centres in the UK is estimated at 55,000 – 60,000. NHS England spends approximately £60 million per year on these services (NHS England. 2020).

There are 35 centres in England that provide specialised prosthetic services (NHS England. 2018).

The 2010-2011 limbless statistics¹ shows the total number of United Kingdom (UK) patients referred for an upper limb prosthetic after an amputation. If we apply these referral rates to the estimated population of the UK in 2020, we might expect 342 people to be referred for an upper limb prosthetic per year. Of these patients, 198 might have benefited from hand prosthetic, 51 patients might have benefited from a partial hand prosthetic and 93 patients might have benefited from a finger prosthetic (University of Salford. 2011, ONS UK population projection for 2020).

Evidence summary

NHS England conducted two independent evidence reviews, one focused on non-myoelectric multi-grip prosthetics and the other focused on myoelectric control multi-grip prosthetics.

NHS England has concluded that there is sufficient evidence to support a policy for the routine commissioning of the myoelectric control multi-grip prosthetic and insufficient evidence for non-myoelectric control multi-grip prosthetics for the indication.

The evidence review which informs this commissioning position can be accessed here:

<https://www.england.nhs.uk/publication/clinical-commissioning-policy-multi-grip-prosthetic-hand-all-ages/>

¹ Limbless statistics is a repository for demographic and clinical quantitative information on only new UK referrals for prosthetics treatment and does not include the whole UK limbless population

Implementation

Additional technical detail is provided in appendix one.

NHS England will routinely commission myoelectric control multi-grip prosthetics in accordance with the patient pathway (see figure one) for patients meeting the following criteria:

Inclusion criteria

- Adult or child² patients, with either unilateral or bilateral³ upper limb loss **AND**
- All upper limb amputation levels (if appropriate for prosthetics) **AND**
- Users who meet the a) initial assessment criteria **AND** b) training/assessment criteria **AND** c) multi-grip myoelectric hand provision criteria outlined below:

a) Initial assessment:

The MDT has considered the individuals limb absence level, concurrent health needs and functional requirements and deemed the individual to be appropriate for a myoelectric multi-grip trial; and there is a potential appropriate device(s) to be trialled which would match the individual for anatomical size, amputation level and functional need. In addition, the user has the:

1. Ability to tolerate and use an upper limb prosthesis consistently **AND**
2. Ability and capacity to utilise and learn the functionality of the myoelectric control multi-grip device:
 - **For paediatric users:** the user is of an appropriate developmental stage to operate the myoelectric control multi-grip device **AND**
 - **All potential users:** are assessed holistically to ensure they have the capacity to utilise the device safely and functionally.

AND

b) Training/assessment:

The potential user meets all of the following training and assessment criteria:

1. Has demonstrated myoelectric control by consistent use of a single grip myoelectric hand over the past 12 months.
2. Agrees to the trial and assessment process with appropriate goal setting for the multi-grip myoelectric control prosthetic trial, using an appropriate clinical tool.
3. Will engage in a period of prolonged and consistent training in both the clinic and day-to-day setting with the myoelectric control multi-grip hand

AND

c) Myoelectric multi-grip hand provision:

This is determined by the MDT after individual patient training and subsequent assessment of function. Individuals will be prescribed a myoelectric multi-grip prosthetic if:

1. A subjective and objective evidence of improved function and outcome with the multi-grip myoelectric control prosthetic as opposed to the single grip hand is demonstrated **AND**
2. The potential user will be engaged in post provision follow-up. This includes ongoing supportive training (as required), an ongoing review of use and suitability

² 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.

³ Given the complexity of control and donning and doffing with the prosthetic this pathway assumes that only one multi-grip myoelectric control device is provided to patients with bilateral upper limb loss unless there are exceptional clinical circumstances to provide a device bilaterally.

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with the multi-grip myoelectric hand and provision for device maintenance and repair.

Exclusion criteria

- An individual is determined to have a contraindication to a trial with a myoelectric multi-grip prosthetic **OR**
- An individual already has a multi grip prosthesis provided and there is no change in prosthetic development or an individual's functional need or clinical condition **OR**
- An individual has completed an assessment with a multi-grip myoelectric control device and shown no additional outcome benefit and there are no new factors which suggest a retriial would be appropriate.

Stopping criteria

Within the multi-grip myoelectric control prosthetics pathway, treatment can be stopped if patients meet any of the outlined criteria below:

a) Training cessation:

Cessation to training should be instigated if there is clear non progression in outcome measures or if the patient is not participating in the training sessions/assessments.

It is recognised that each patient is unique and this needs to be discussed with the patient, occupational therapist and consultant in rehabilitation, who will have the overall responsibility to make the decision to halt the assessment process.

Training could be restarted after a suitable passage of time to be decided between the MDT and the patient, it would be expected that this would be no sooner than 6 months after the initial trial.

b) No functional outcome benefit:

If an individual does not demonstrate an improvement in functional outcome measures as assessed by the weighted subjective and objective assessments at the end of a suitable device trial.

c) A multi-grip myoelectric control prosthetic is no longer an appropriate intervention:

An individual's functional need, health status or suitability changes to the extent to which a multi-grip myoelectric control prosthetic is no longer an appropriate intervention, as assessed by the MDT.

The patient can exit the pathway at any point if they determine they do not wish to continue the training or evaluation for a multi-grip myoelectric control prosthetic.

d) Abandonment of multi-grip myoelectric control prosthetic:

Cessation of provision should be instigated if the patient does not use the prosthesis on a regular basis. The use of the prosthesis will be assessed on regular six-monthly review appointments with the consultant, occupational therapist or prosthetist with appropriate outcome measures.

Patient pathway

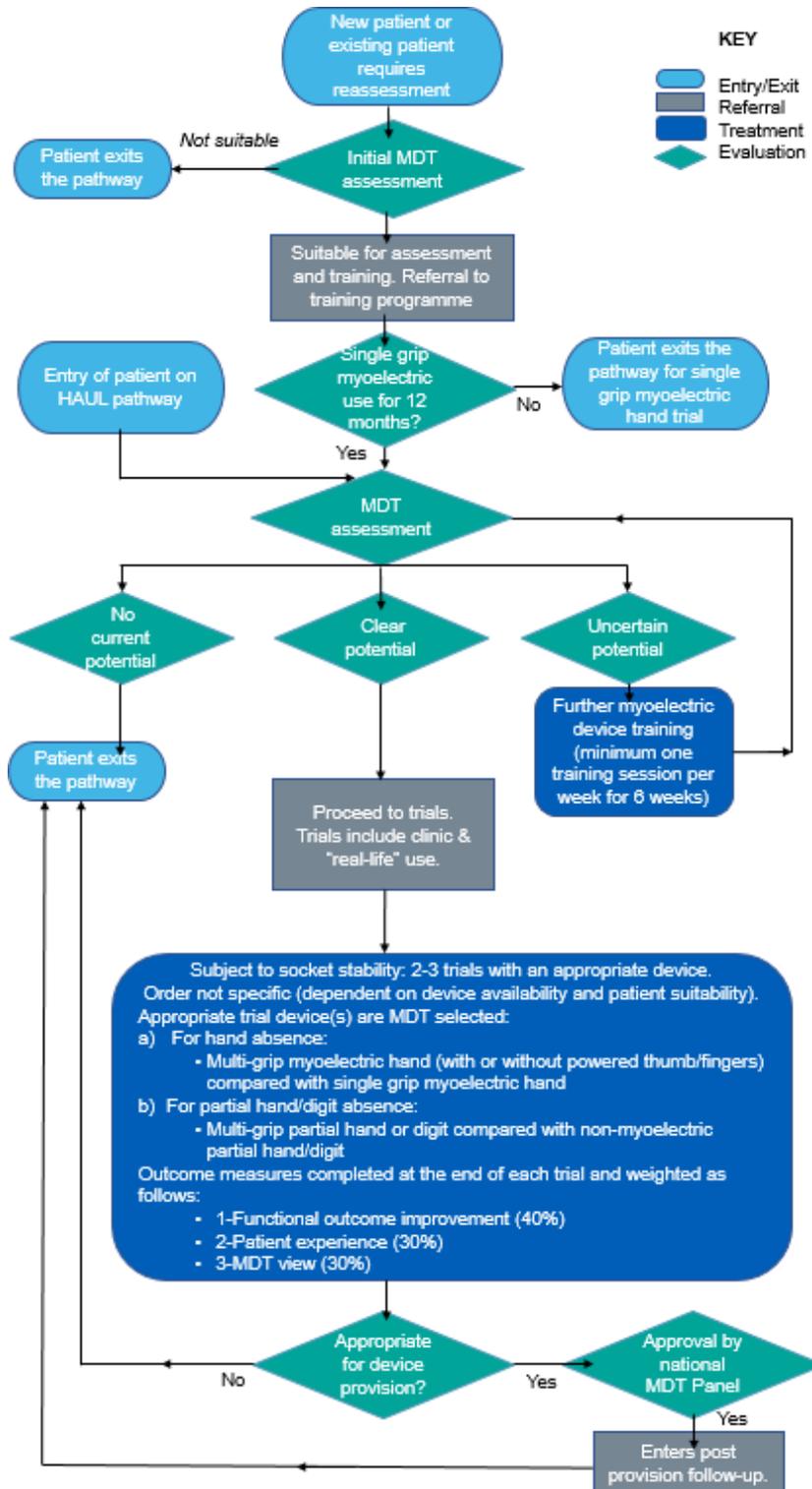
The pathway (figure one) treats patients as individuals, with unique functional and personal objectives. The initial assessment of suitability to enter the pathway is built upon individual goals and objectives with the myoelectric control prosthetic.

The post provision pathway includes follow-up assessment for ongoing training, support and device maintenance and repair.

Patients on the Hand and Upper Limb Transplant (HAUL) pathway

As an inclusion criterion for hand and upper limb transplant, patients need to be unsuitable for current available prosthetics. This pathway is integrated within the multi-grip myoelectric control assessment process (figure 1).

Figure 1-Patient pathway for a multi-grip myoelectric control prosthetic device



Governance arrangements

Any provider organisation treating adult or child patients with this intervention will be required to assure itself that the internal governance arrangements have been completed before the intervention is prescribed. NHS England may ask for assurance of this process or documented evidence that these processes are in place.

The governance arrangements are described in detail within Service Specification D01/S/d for Complex Disability Equipment (all ages) and Service Specifications 1685, Hand and Upper Limb Transplant Service (adults).

The providing centre for multi-grip myoelectric control prosthetic hands should have an appropriately trained MDT which includes a consultant, occupational therapist and upper limb prosthetist all of which are trained within amputee rehabilitation. The staff should have appropriate training and experience in the use of a multi-grip myoelectric control prosthetic.

Centres providing the provision of paediatric upper limb prosthetics should have appropriate and separate upper limb treatment rooms, providing a child focused environment. Clinical staff providing rehabilitation to children, should be appropriately skilled and trained in child rehabilitative needs.

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

Mechanism for funding

The funding and commissioning will be managed through the relevant local NHS England Specialised Commissioning Team.

Further work will list the multi-grip myoelectric devices commissioned under this policy, based on a cost and device availability assessment. It is anticipated that this will align with the terms of reference used for Veterans Prosthetic Panel, by which equipment over and above a cost threshold (anticipated to be £20, 000 excluding VAT) is not ordinarily funded.

Audit requirements

An intervention specific audit dataset will be agreed nationally and collected locally. This includes the number of patients assessed for a multi-grip myoelectric control device (adult/child numbers and the amputation level). The outcome measures of patients assessed under the patient pathway and the number of patients provided with a multi-grip myoelectric prosthetic device (including device provided) should be documented.

For patients provided with a multi-grip myoelectric control prosthetic device, the outcome measures from six-monthly review appointments (including prosthetic abandonment and the frequency of device repair) should be documented.

The outcome measures will be collated from the national database and reported back to the National Clinical Reference Group (CRG) annually by the subcommittee. The annual assessment will allow a demonstration of the outcomes of the policy and also allow potential recommendations for policy revision (through the policy revision pathway). The subcommittee can also advise on new devices, which may be appropriate for inclusion on the commissioned multi-grip myoelectric device list. Device list amendments would be conducted through the policy revision pathway, based upon financial and device availability assessment.

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.

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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.

Definitions

<p>Activity based terminal device prosthetic</p>	<p>An individually designed prosthetic with a specific task in mind. The device is adapted for the user, e.g. a prosthetic which accommodates a utensil to assist with eating or a prosthetic which is adapted to hold a tool.</p>
<p>Body powered prosthetic device</p>	<p>A device which is controlled by the remaining muscles or the opposite side using a pulley mechanism or connecting joints in the device. This type of prosthetic can have a hook or hand which only open and closes in one direction (a single grip) or connecting mechanisms which allow the user more than one grip pattern (a multi-grip device).</p>
<p>Myoelectric controlled prosthetic device</p>	<p>Electric-powered prosthetics, known as myoelectric prosthetics, are controlled by coordinated patterns of movements in the remaining limb which activates sensor-controlled motors in the device. The motors allow movement through articulated thumb and fingers within the prosthetic hand. There are different models of device available depending on the pattern of limb loss. This includes hand, partial hand and digit prosthetics with the required wrist, elbow and shoulder adaptations, dependent on the amputation level. Some device models have either a powered or unpowered thumb. The device can be single grip (one grip pattern) or multiple-grip (more than one grip pattern).</p>
<p>Passive functional prosthetic device</p>	<p>A device which has been known in the past as a cosmetic or replica hand. This prosthetic has no moving parts, but can help the user with the appearance of limb loss. The passive functional prosthetic can also help with non-grasping tasks, such as pushing and pulling objects or holding something steady while the opposite side performs a task. The new term reflects the prosthetic has a greater role than just replacing the hand in appearance.</p>

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Appendix one

Implementation technical detail

Appropriate prosthetic trial:

The aim of the prosthetic trial is to provide the patient with the best prosthesis via a thorough assessment, based on their individual need. It is recognised that not all the different types of prosthetics can be trialled and to this end the various myoelectric multi-grip prosthetics have been categorised into groups which will be triaged with appropriate outcome measures.

The use of video and remote clinics would be encouraged to reduce the burden for patients, within the assessment pathway.

Proposed key elements include:

- An initial assessment of the patient and their functional need. Performed by an MDT member (likely the prosthetist). This assessment considers the user and available and suitable prosthetic hand options.
- The user is presented with the possible options and the benefits and challenges of each device are highlighted. The user is encouraged to be part of this process, directed to accessible patient facing information about the devices.
- Appropriate devices are selected for a trial (possibly 1-3). The componentry are checked for the trial. There is an assessment of socket fit with the device.
- It is noted that the assessment and training for each individual will vary. The pathway needs to incorporate time for users to understand and learn the functions of a more advanced terminal device, with key members of the MDT team providing support.

The representative categories of prosthetic device to be trialled include:

- a. Patients with hand absence:
 - Myoelectric control multi grip prosthetic with manual thumb or powered thumb/fingers
 - Comparison with the myoelectric control single grip prosthesis.
- b. Patients with partial hand and digit absence:
 - Myoelectric control multi-grip - I limb digits: suitable for digit loss and partial hand amputees
 - Comparison (dependent on amputation level):
 - Either non-myoelectric control single grip transcarpal prosthesis: only suitable for complete transcarpal amputees (all fingers and thumb) **OR**
 - Non-myoelectric control multi-articulating prosthetics: suitable for finger amputations at the proximal phalanx level.

Outcome measures:

The aim of the pathway is to be patient centred. Prosthetic provision is based on 3 elements:

1. Patient experience view (e.g. quality of life measures) (30% weighted)
2. The knowledge and experience of the MDT (30% weighted)
3. The functional outcome improvements, assessed through appropriate clinical tools. Suggested tools include: Disability of Arm, Shoulder and Hand (DASH) or Southampton Hand Assessment Procedure (SHAPs) or Canadian Occupational Performance Measure (COPM) pre and post intervention (40% weighted)

This cumulative outcome score will then determine multi-grip myoelectric control device provision.

Appropriate prosthetic provision:

After a suitable trial period and assessment, the decision will then be made by the MDT and a consultant will prescribe based on the cumulative weighted outcome measure. This includes the patients account of preferred prosthesis and the MDT's recommendation.