Clinical Commissioning Policy: Provision of custom made high definition silicone covers for prosthetic limbs and partial hand prostheses

Reference: NHS England DO1/S/d

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Contents

Policy Statement

NHS England will commission routinely commission 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

This policy relates to the provision of treatment for patients who have been born with, or have acquired through illness or accident (including as a result of military action), the loss of a limb or part of a limb.

It relates to the provision of custom made high definition silicone covers or partial hand prostheses provided to a cohort of patients where it is deemed that it forms an integral part of ensuring the successful prosthetic rehabilitation.

There are approximately 55-60,000 people in the UK who are users of the prosthetic services. Given the qualifying criteria provided in the body of this policy, it is estimated that the cohort of prosthetic users who would be eligible for this treatment on the NHS would be approximately 550-750 people.

Given the evidence available and the feedback from the patient participation groups, this policy recommends that NHS England should commission this treatment in accordance with the agreed eligibility criteria.

1. Introduction

Historically, prostheses were only considered functional if they enabled individuals to perform physical tasks, permit the body to move, or enable any number of active functions not previously capable without a prostheses. This perspective has changed over the years and many health care providers now recognise that the functionality of cosmetic prostheses add significantly to a successful prosthetic rehabilitation. For some users the provision of a very life like cover for a prosthesis is of vital importance.

2. Definitions

For the purposes of this policy there are two main uses relating to silicone prosthesis which require clarification. The first relates to prosthetic devices where the use of silicone is an integral part of the functional requirements of the prosthesis itself, for example silicone partial feet prosthesis. Silicone partial feet prosthesis are not covered by the scope of this policy and should be considered as part of normal prosthetic provision.

The second definition refers to custom made high definition silicone covers and custom made partial or whole hand prosthesis colour matched to the individual.

3. Aim and objectives

This policy aims to :

Identify the criteria against which the provision of a custom made high definition silicone cover or partial hand prosthesis forms an integral part of the successful rehabilitation process and use it to make policy recommendations.

The objectives are to:

- Identify whether this treatment should be funded by NHS England
- Review the evidence available to support the decision of this policy
- Establish the criteria against which any patient would need to be assessed
- Identify the size of patient cohort who would be eligible for this treatment and the potential cost implications to NHS England

4. Epidemiology and needs assessment

The provision of this treatment could potentially cover all patients with acquired or congenital loss of limb or part of a limb registered with a specialist rehabilitation centre in England, In total this is estimated to be approximately 55-60,000 people in the UK.

However given the selection criteria indicated above, the small number of patients presenting with the loss of parts of a hand and the number of requests for custom made high definition silicone covers received in the centres in the past it is

estimated that this would be in the region of 550 patients per year with an approximate cost of £2.25m in the first year.

These costs would increase in subsequent years as in addition to new patients being qualifying for the provision of a HD silicone cover some of the previously provided covers will require repair or replacement.

These costs would increase incrementally between years 1-3 as more "new" patients are provided with the covers and those patients who had previously been successful in their application for "exceptional funding " to the PCT would require a replacement.

As the HD silicone covers are expected to have a lifespan of 3 years they would, in the main, require replacement by year 4. This would result in estimated costs to the NHS of approximately £5.5m in that, and subsequent, year with a full cohort of new patients and all the "year 1" patients requiring a replacement.

5. Evidence base

There are a number of papers which have been published and refer to the impact that the appearance of a prosthetic limb or device may have on the successful prosthetic rehabilitation of a patient with acquired or congenital loss of limb or part of a limb. In particular the evidence supports the potential impact of the quality of life for this cohort of patients and their ability to participate fully in society. The overall costs of providing custom made high definition silicone covers or partial hand prosthesis to these patients are very low in relation to the costs of healthcare provision in the UK and the current spending provided for the provision of prosthetic services in the UK.As with other areas of prosthetic provision the small numbers of patients and the difficulty in undertaking randomised clinical trials makes it very difficult to provide a large, validated bases of evidence to support this policy.

A systematic review undertaken to establish what is known about adult user's perceptions of upper limb prostheses in terms of both cosmesis and function (Ritchie et al 2011). It reported that while users of cosmetic prostheses were mostly satisfied with their prostheses, satisfaction rates vary considerably across studies, due to variability in demographics of users and an ambiguity over the definitions of cosmesis and function. Design priorities also varied, though overall there is a slight trend toward prioritising function over cosmesis. The reviewed studies mostly examine functionality and cosmesis as separate constructs, and conclusions are limited due to the disparity of user groups studied. Therefore, the authors made recommendations for further work to explore understandings of these constructs in relation to upper limb prosthesis use.

However the expertise of the groups charged with developing this policy along with feedback from a number of patient groups leads us to believe that what evidence we have reviewed would, as defined by GRADE, meet the requirements of strong, high quality evidence in relation to the quality of life improvements and cost effectiveness of this treatment protocol. It would enable many of this cohort of patients to integrate fully back into society, including returning to education or work, and would reduce the potential requirement for longer term social and psychological care input..

6. Rationale behind the policy statement

This Policy statement endeavours to highlight the specific needs for a small number of patients suffering for the loss or all or part of a limb. It aims to show that successful rehabilitation for these patients requires a prosthetic device which not only meets their functional requirements but also has a “life like” appearance which meets their, or their family or carers, psychological needs.

As amputation or congenital limb loss is a life- long condition the potential long terms impact of dealing with the psychological aspects of this specialist area of care cannot be underestimated. The personal rehabilitation goals of individuals requiring this treatment will change during their lifetime. However the evidence reviewed and the anecdotal feedback provided by the patient participation groups and healthcare professionals involved in developing this policy supports the belief that the provision of custom made high definition silicone covers and partial hand prostheses enables eligible patients to participate fully in society including undertaking full time education, employment and hobbies and recreational pursuits.

7. Criteria for commissioning

INDICATIONS

- Demonstrable severe psychological distress related to body image following the loss or absence of a limb or part of a limb and confirmed by a qualified specialist psychological assessment
- Demonstrable severe psychological distress related to body image for a parent or carer of a child following the loss or absence of a limb or part of a limb and confirmed by a qualified specialist psychological assessment
- Required to enable the user to integrate fully back into social or occupational situations, agreed as part of their clinical or rehabilitation goals, leading to an improved quality of life outcome (use of QoL assessment) as agreed following psychological assessment
- Established adult prosthetic user with a definitive prescription and with no socket intervention or components changes in the past year
- Have shown significant benefit from use of low definition prosthetic covers over the standard prosthetic finish

CONTRAINDICATIONS

- Inability to tolerate the additional weight of the cover
- The provision of a cover would reduce the clinical effectiveness or functionality of the prosthesis being prescribed
- The user has a Track record of not looking after prosthetic limbs or cosmetic covers
- Fluctuating stump volumes requiring regular new sockets and intervention
- New patient – with the exception of partial hand patients or military Veterans

(See Appendix 1 of Complex Disability Equipment Specification Do1/S/d)

- Occupational factors such as kneeling or crawling likely to result in abrasion to silicone high definition cover
- Environmental factors including excessive heat, oil, sand or sea water

4.3 ADDITIONAL PRESCRIPTION CRITERIA

- Custom made high definition silicone covers will normally only be available for the below knee or below elbow section of a prosthetic limb and will not cover a functional joint

Any custom made high definition silicone cover will be expected to last 2- 3 years, with the exception of those provided to children where changes to the length of a prosthesis as a result of growth is recognised as a normal part of their rehabilitation.

8. Patient pathway

Patients would be registered at one of the network of Specialist Rehabilitation Centres in England, or with another NHS approved provider. The patient would be assessed by the Multi-disciplinary team in the centre, including assessment by a qualified clinical psychologist with experience of working with patients with physical disabilities, to ascertain their clinical and rehabilitation requirements.

The patient, with the exception of those requiring a partial hand prosthesis, will be recognised as an established patient with limb loss as described in the Service Specification Do1/S/d – "*These patients have undergone a period of rehabilitation and re-ablement following the loss of a limb and achieved their maximum potential in terms of mobility and independence*"

The patient will have requested to be provided with a custom made, high definition silicone cover to facilitate the final stages of their rehabilitation process.

9. Governance arrangements

This service falls under the governance arrangements highlighted in the Service Specification for Complex Disability Equipment – Prosthetics (D01/S/d)

10. Mechanism for funding

Custom made high definition silicone covers and partial hand prostheses will be provided through the network of specialist Prosthetic Rehabilitation centres. These centres are funded under specialist commissioning status from NHS England and it is expected that this treatment would be provided under the same funding mechanism.

11. Audit requirements

The on-going effectiveness of this treatment should be audited on a national basis by all service centres

Outcomes related to the implementation of this policy, participation, goal achievement and assessment criteria should be audited

Data relating to patient numbers, demographics, and levels of amputation should be provided by the national network of centres and made available to NHS to enable them to estimate on-going requirements for this treatment. They will also be necessary to ensure accurate updating of this policy.

12. Documents which have informed this policy

Department of Health (2010), Equity and excellence: Liberating the NHS: section 3 Putting the patients and the public first, Department of Health, London

CES (2010), Patient-led Prosthetics Services Charter, emPOWER consortium of charities, 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.audit-commission.gov.uk/auditcommission/nationalstudies/health/socialcare/pages/fullyequipped.aspx.html

Audit Commission (2002), Fully equipped: Assisting independence, London http://archive.audit-commission.gov.uk/auditcommission/nationalstudies/health/socialcare/pages/fullyequipped2002.aspx.html

Audit Commission (2004), Guidance on the commissioning of prosthetics services, London, http://archive.audit-commission.gov.uk/auditcommission/SiteCollectionDocuments/AuditCommissionReports/NationalStudies/olderpeopleprosthetics.pdf

13. 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).

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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