



Clinical Commissioning Policy: High definition silicone covers for prosthetic limbs, high definition feet and partial hand prosthesis

Reference: NHS England D01/P/a

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1 Executive Summary

Policy Statement

NHS England does not routinely commission high definition silicone covers for prosthetic limbs, high definition feet and partial hand prostheses.

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

Equality Statement

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

Plain Language Summary

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 prosthetic services.

2 Introduction

This policy relates to the provision of prosthetic rehabilitation services and medical devices for patients who have been born with, or have acquired through illness or accident, the loss of a limb or part of a limb.

This policy relates specifically to the provision of custom made silicone covers, high definition silicone foot and partial hand prosthesis. These custom made silicone covers, high definition silicone foot and partial hand prosthesis are manufactured on an individual basis and more closely match the individual patient's skin colour and appearance.

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.

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 a policy for routine commissioning.

3 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 prostheses colour matched to the individual.

4 Aims and Objectives

This aims and objectives of this policy are to set out the NHS England commissioning position for high definition silicone covers for prosthetic limbs, high definition feet and partial hand prostheses.

5 Epidemiology and Needs Assessment

The clinical commissioning policy would 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, 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 policy would affect in the region of 550 patients per year.

6 Evidence Base

NHS England considered the available clinical evidence as described by the Clinical Reference Group. NHS England concluded that there was not sufficient evidence to support the routine commissioning of this treatment for the indication.

The literature search identified a systematic review which aimed to establish what is known about adult user's perceptions of upper limb prostheses in terms of both cosmesis and function. It undertook a comprehensive search and identified 15 papers.

The majority of the papers (12) used questionnaires to collect data from participants, either by post or using online tools. Only three of the papers used other methods: semi-structured interviews and case studies. Five of the papers examined both adults and children six focused only on adults. The remaining four studies did not specify the age range, though in most cases it is likely that they referred only to adults.

The main themes arising from the review were user satisfaction ratings with current prostheses, priorities for future design and the social implications of wearing a prosthetic limb. 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 qualitative studies noted the importance users placed on presenting a 'normal' appearance and 'not standing out'.

There were several weaknesses within the study as it reviewed studies which mostly examine functionality and cosmesis as separate constructs, and its conclusions are limited due to the disparity of user groups studied. There are also issues concerning the way in which users' perceptions of cosmesis and function are examined (i.e. the methods used) within the studies. Another issue with the review was related to the exclusion of 15 papers widely cited elsewhere in the literature which is a potential bias in the findings.

There were no studies which were found on lower limbs or cost-effectiveness studies. Based on the currently available literature, it is concluded that further work to explore understandings of users' perceptions of functionality and cosmesis constructs in relation to upper and lower limb prosthesis use is needed.

7 Rationale behind the Policy Statement

High definition silicone covers for prosthetic limbs, high definition feet and partial hand prostheses has been considered by NHS England, which concluded that there was not sufficient evidence to support a policy for routine commissioning.

8 Criteria for Commissioning

NHS England does not routinely commission high definition silicone covers for prosthetic limbs, high definition feet and partial hand prostheses.

9 Patient Pathway

Not applicable.

10 Governance Arrangements

Not applicable.

11 Mechanism for Funding

NHS England will not routinely fund high definition silicone covers for prosthetic limbs, high definition feet and partial hand prostheses for patients with limb loss.

12 Audit Requirements

Not applicable

13 Documents which have informed this Policy

Not applicable

14 Links to other Policies

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

15 Date of Review

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

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