Assessment of External Prostheses in Upper limb Amputees

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BACKGROUND

- Since 2005, HAS has assessed medical devices to establish which ones qualify for reimbursement. If they do, they are included in the “List of products and services qualifying for reimbursement” after agreement from the Ministry of Health.
- Up to now, upper limb prostheses have been reimbursed by the French National Health Insurance Fund, based on generic descriptions*: “work”, “service” and “social life” prostheses.
- As these descriptions are no more clinically relevant, they need up-dating with regards to amputees’ needs.

OBJECTIVES

To redefine and to up-date the generic descriptions of upper limb prostheses qualifying for reimbursement, according to technical characteristics, indications and prescription conditions.

METHODS

Systematic search
- Medline, National Guidelines, Cochrane Library, Embase, Pascal, HTA database, learned societies web site.
- Manufacturers’ data.
- n=1 080 papers retrieved.

Critical assessment of clinical data
- Pre-specified criteria for selection of studies.
- Study design quality.
- n=14 papers selected.

Multidisciplinary working group discussions
- 6 experts, members of multidisciplinary care teams, recruited from learned societies: SFOMER, AFA, AMPAN.
- 2 years appraisal.
- 9 meetings.

HAS appraisal and validation by the National Committee for the Evaluation of Medical Devices and Healthcare Technologies (CNEDIMTS).

RESULTS

Methodological specificities of this assessment
- Many available publications. Few of clinical relevance.
- Low methodological quality.
- Assessment relying on the clinical expertise and feed-back of the working group.

A new modular classification
- 57 generic descriptions of sockets, according to amputation level, terminal device actuation mode and socket fixation type.
- 114 generic descriptions of prosthetic components, including terminal devices, joints, liners, actuators, accessories and cosmetic covers.

HAS recommendations
- Actual benefit of upper limb prostheses is confirmed.
- HAS recommends a classification based on the actuation mode of the prosthesis terminal device: inert, passive, mechanically active and electrically active prostheses.
- These four prostheses types offer different functions corresponding to various prehension activities. To meet each amputee’s needs, they all have to be available and reimbursed.
- Regarding inert prostheses HAS recommends that custom-made cosmetic covers, not funded yet, should be reimbursed.

Estimated target-population

In France, the population with upper limb amputation (acquired and congenital limb deficiency) is not known. Neither is the number of upper limb amputees who wear prosthesis.
An estimated 2100 upper limb prostheses are annually covered in France, of which:
- 1,800 rely to major amputations (wrist disarticulation and above); 280 cases are new referrals,
- 300 concern minor amputations (finger(s) and partial hand amputations); 80 cases are new referrals.

CONCLUSIONS

HAS has provided:
- a new patient centered modular classification of generic descriptions for upper limb prostheses;
- a clinically relevant prescription guide for prostheses tailoring each amputee’s needs;
- a useful tool to improve prosthetics practice and use, from design to fabrication and amputee’s feedback.

* A generic description identifies a category of medical devices which comply with the same technical specifications and are reimbursed under the same conditions (indications, conditions for prescription and use, price).