HAUTE AUTORITÉ DE SANTÉ

ASSESSMENT OF BREAST IMPLANTS, TISSUE EXPANDERS AND EXTERNAL BREAST PROSTHESES

REVISION OF CATEGORIES INCLUDED ON THE LIST OF PRODUCTS AND SERVICES QUALIFYING FOR REIMBURSEMENT :
"EXTERNAL BREAST PROSTHESIS, BREAST IMPLANT AND TISSUE EXPANDER"

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Medical Devices Assessment Department

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Working group

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We give thanks to the following professionals for their careful reading of the report:

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In line with decree 2004-1139 dated 26 October 2004 (art. R. 161-84 to R.161-86 of the French Social Security Code), all members of the working group have completed a public declaration of interest, the aim of which is to inform HAS about any conflict of interest that could arise based on group members' relationships with manufacturers. The members of the working group declared any conflicts of interest they might have at the start and end of the project.
Under the criteria laid down in the HAS “Guide on declaration of interests and prevention of conflict of interest”, none of the members of the working group are considered to have a conflict of interest.

The working group was set up following proposals from the learned societies consisting of the relevant specialists.

The working group’s opinion as presented in this dossier has been ratified by each of its members.

Summary

Background

In order to be reimbursed by the French national health insurance, medical devices must be registered on a list known as the List of Products and Services qualifying for Reimbursement (LPPR). Products are included either under a common description covering a class of products with the same indications and with common technical characteristics (generic description) or individually registered under the product's commercial name (brand name). The HAS Committee for the Assessment of Products and Services (CEPP) is responsible for the medical assessment of these products.

The aim of this current project is to revise the categories “External breast prosthesis, breast implant, tissue expander”.
In 2009, external non-solid silicone breast prostheses and external fluid-filled prostheses are reimbursed by the French national health insurance, with no indication specified. Just one type of adhesive silicone prosthesis is reimbursed following mastectomy (Amoena Contact, made by Amoena France).
Breast implants that are reimbursed are textured implants of any shape. Implants are reimbursed if the indication is breast reconstruction, with the exception of exclusively cosmetic procedures.
The types of tissue expanders that are reimbursed by the French national health insurance are either smooth, textured with integrated valve or textured with a self-closing valve. Indications are stated for each class of tissue expander: in breast reconstruction for textured and smooth expanders, in plastic and reconstructive surgery under defined conditions for smooth expanders [significant loss of tissue (burns, trauma or following extensive excision of naevi or tumours) as an alternative to skin graft; congenital facial malformation, particularly in children].

Working method

HAS has carried out an assessment of the actual clinical benefit of these medical devices. The method used in this document is based on analysis of the data from the scientific literature, data from manufacturers and service providers and on the views of healthcare professionals brought together in a multi-disciplinary working group. The members of the group declared any conflicts of interest they might have at the start and end of the project.
The literature from was surveyed using a search of the main medical literature databases *(Medline, The Cochrane Library, National Guideline Clearinghouse and* the HTA Database), with the search limited to between 2000 and October 2008.
The working group gave its opinion on the actual clinical benefit of these products, conditions for prescribing and use and indications and conditions for inclusion on the LPPR, using a critical analysis of the literature and of dossiers submitted by manufacturers.

The working group’s proposals and the planned nomenclature arising from the proposals have been sent to manufacturers, service providers and patient associations, as well as to representatives from French health insurance organisations, the French directorate general of health, the French social security directorate and national cancer institute.
Subsequently, the CEPP examined the group’s proposals and issued recommendations to the minister.

External breast prostheses

Critical analysis of the data

A literature search on the use of external prostheses had limited results. Of the 49 studies found, 3 were analysed. The endpoints analysed were satisfaction, quality of life, and complication rates.
Results of these studies showed overall patient satisfaction levels of around 65%, and a quality of life score of around 60 out of 100, regardless of the type of prosthesis used. Complications, which were examined in one study, involved skin rash, which was observed in 2% of patients with prostheses with Velcro fastenings.
Comparative data, which were taken from a study that compared adhesive with non-adhesive prostheses, showed no difference in terms of overall satisfaction.

Working group opinion

The working group recommends that external silicone prostheses, whether adhesive or non-adhesive, continue to be reimbursed, and that there be a specific reimbursement procedure for textile prostheses, which are not currently reimbursed by the French national health insurance. The group no longer recommends reimbursement of external fluid-filled prostheses, given the other available prostheses types. Distribution procedures for all external prostheses have also been given. The group wishes to emphasise the need to make all types of these prostheses available.

- Silicone prostheses

The group wanted to divide silicone prostheses into two classes: non-adhesive prostheses and adhesive prostheses. Adhesive prostheses may or may not have an adhesive pad. Adhesive pads were designed to replace fastenings (e.g. Velcro) which are no longer useful given the development of new fastening types which are more suitable. They enable the prosthesis to adhere for a mean period of 6 months.
Indications are as follows: total mastectomy, congenital or acquired asymmetry, major hypoplasia and aplasia.
Technical specifications for external silicone prostheses have been updated, with no major amendments to the specifications given previously.
A generic description of adhesive silicone prostheses will also enable inclusion of adhesive silicone prostheses (with or without adhesive pads). The packaging for adhesive prostheses with pads will include two adhesive pads per prosthesis.

- Textile prostheses

These are useful in that they provide light textile prosthesis for women who do not undergo immediate breast reconstruction, which can be placed directly over the scar after the operation. Such prostheses are generally used temporarily.
Currently, such prostheses are not reimbursed, and not all women receive this type of prosthesis after surgery, mainly because of a lack of information.
Indications are as follows: total mastectomy, congenital or acquired asymmetry, major hypoplasia and aplasia.
The group proposed one reimbursement of theses protheses per patient. It must also be possible to reimburse for one silicone prosthesis during the same year.

- Fluid-filled prostheses

These prostheses are no longer used in France. The group does not recommend that they continue to be reimbursed.

Distribution methods for external prostheses have been given, including the requirement for specific training for distributors, availability of samples of each type of external prosthesis, obligation to try the product before delivery, and making sure premises are equipped to maintain patient privacy. The group wishes to emphasise the importance, particularly for prescribers and distributors, of informing the patient about the various types of prosthesis and about how to use the chosen prosthesis type.

Tissue expanders

Critical analysis of the data

A literature search for studies involving tissue expanders showed that these studies are limited in number and of poor methodological quality (there are no randomised comparative studies). Results were separated by indication : mammary or non-mammary.
Of 138 references identified that had mammary indications, with prior tissue expansion, 16 studies were included. Results showed satisfaction levels of between 82% and 95%, and a quality of life of between 65 and 88 out of 100, regardless of the type of prosthesis analysed. The main complications were capsular contracture (at a rate of around 4% at 2 years and 21% at 5 years), seroma or hematoma, and infection. A retrospective study to evaluate locoregional and distant cancer recurrence in 618 patients at 5 years showed no difference between women with breast implants and those without, following tissue expansion.
In the studies that were analysed, provisional expanders were not evaluated independently from breast implants. Results show that tissue expanders does not affect quality of life, patient satisfaction or complication rates. Comparative data, from a non-randomised study, showed no significant difference in terms of rippling between saline and silicone gel implants following tissue expansion. These data come from a study that had methodological biases.

Of 13 references identified that had non-mammary indications (in particular burns, congenital abnormalities and trauma) 8 studies were included. Only complications were analysed. The complication rate for expanders varies between 10% and 25%, regardless of the type of expander. Comparative data, which were taken from a study that had methodological bias, showed no difference between the shape of the expander and the technique's failure rate.

Working group opinion

There are three categories of prosthesis: smooth (provisional), textured (provisional) and permanent expanders. These types of prosthesis have actual clinical benefit and the working group recommends that surgeons be able to use all three categories of implant. Indications and technical specifications have been updated, with no major amendments to those given previously. For non-mammary indications, only smooth expanders are used. Indications are loss of skin which mean closure is not possible without excessive tension, and treatment for congenital or acquired malformation. For mammary indications, all three categories of prosthesis are used. Indications are breast reconstruction and treatment for congenital or acquired breast malformation.
Conditions for prescription and use have been laid down, so that prostheses can be reimbursed under the same conditions as those stated in the joint classification of medical procedures (CCAM).

Breast implants

Critical analysis of the data

A literature search found 396 references, of which 48 articles were included: 4 for the indication involving breast reconstruction with no prior tissue expansion, 9 for indications involving breast reconstruction and augmentation, and 35 studies on breast augmentation with cosmetic indications.

The methodological quality of the trials was as follows: 2 meta-analyses, 1 systematic review, 3 randomised comparative prospective studies, 16 non-randomised comparative prospective studies, 6 non-comparative prospective studies, 12 comparative retrospective studies, 8 non-comparative retrospective studies.

For indications involving reconstruction without prior tissue expansion following breast cancer, patient satisfaction, which was evaluated in just one study, was assessed as good or very good in 51% of cases. There were no studies that assessed quality of life. At least one post-operative adverse event was observed in 60% of patients at 44 months. The most common adverse effect was grade III-IV capsular contracture, which occurred in between 4% and 20% of cases, and which required repeat intervention in 1 in 5 cases. Displacement, asymmetry and deflation occurred at rates of 11%, 11% and 7% respectively. A retrospective study has been done on cancer recurrence and mortality, in which sub-group analyses not planned for in the protocol were carried out. This study showed lower levels of long-term mortality and breast and lung cancer mortality in 817 women with implants in comparison with 3568 women without implants. This study showed no difference between occurrence of cancer and the type of implant used. However, the methodological bias of this study makes it difficult to interpret its results.

For both indications (reconstruction without prior tissue expansion following breast cancer and cosmetic surgery), patient satisfaction was assessed as good or very good in 90-98% of cases. In one study, sub-group analysis showed that satisfaction scores for smooth implants were significantly higher than for textured implants. There are, however, methodological biases in this study. There were no studies that assessed quality of life. The most common complication was grade III/IV capsular contracture, with a frequency of between 0.8% and 20.5%. Comparative data involving smooth and textured implants, seen in one non-randomised study, showed no significant difference in terms of capsular contracture (grade III/IV) and rates of rupture. However, this study showed that rates of deflation and abnormal waviness or rippling were greater for textured implants than for smooth implants. In addition, results concerning hydrogel implants show significant numbers of complications, in particular a 32% capsular contracture rate and high rates of deflation (40%) compared to those observed for saline implants. All comparative data were taken from studies that had significant methodological bias (lack of randomisation, sub-group analysis not planned for in the protocol, etc). There were no studies that assessed cancer recurrence or mortality.

For cosmetic surgery, the percentage of women who were satisfied ranges between 89% and 99%. No statistical difference could be shown between smooth and textured implants or between round and anatomically shaped implants. Results of studies on the quality of life of women with saline and silicone gel breast implants were satisfactory (mean score of 9 on a scale of 1 to 10, and no difference in quality of life score between women with implants and the general population). There were no studies that compared the quality of life of patients with different types of implant. Results in terms of complications indicate a complication rate of 4% at 6 years and a rate in the order of 27-36% after 11-13 years. The complication rate depends on the generation of implant used and the length of follow-up. The most commonly observed complication was capsular contracture, with a frequency of between 0.5% and 20%. Comparative data for various types of implant were mainly taken from studies that had methodological biases, in particular non-comparable groups and multiple comparisons.
In terms of cancer risk, in the 8 articles analysed there was no increased risk of cancer (all cancers) in women with breast implants, after a mean period of between 8 and 18 years, in

groups of 1600-30,000 women. In the 7 articles analysed there was no increase in the risk of breast cancer, after a mean period of between 8 and 18 years, in groups of 1600-30,000 women. Two studies showed an increased risk of lung cancer, after a mean period of between 15 and 18 years, in a group of around 3000 patients. However, in one study the group of patients with implants was shown to have a higher rate of smoking than the general population, and this was not assessed in the other study. The groups of patients were not comparable, which limits the validity of these results.
Finally, all-cause mortality results were discordant (three studies showed a difference, and three studies showed no difference, between groups of patients with and without implants). No increase in breast cancer mortality was observed in the five studies that used this criterion, in groups of 3500-40,000 women, after mean periods of between 9 and 18 years. These results emerged from studies that used poor methodology, which limits the usefulness of interpretations of their results: confounding factors, patient selection bias, multivariate analysis, etc.

In conclusion, few studies have been carried out on breast reconstruction following breast cancer. Most studies have been carried out on cosmetic surgery. The majority of studies had methodological bias, in particular lack of randomisation (confounding bias and patient selection), and multiple comparisons that were not planned for in the protocol. The results of these studies are difficult to interpret. In addition, the majority of studies included older-style implants than those currently used.

Working group opinion

It is confirmed that breast implants have actual clinical benefit in breast reconstruction and breast augmentation that are reimbursed by the French national health insurance. The group proposes that breast implants be distinguished by shape (round or anatomical). The group recommends that surgeons be able to use both categories of implant.

The indications for reimbursement have been redefined, and the approved indications are now breast reconstruction or augmentation that are reimbursed under the Joint Classification of Medical Procedures (CCAM) as laid down in article L. 162-1-7 of the Social Security Code. The procedures involved for reimbursement are as follows:
- QEMA003: Unilateral augmentation mammoplasty, with insertion of prosthetic implant
Indications: major asymmetry requiring compensatory bra adjustment, malformation syndrome (tuberous breast and Poland syndrome);
- QEMA004: Bilateral augmentation mammoplasty, with insertion of prosthetic implant
Indications: bilateral breast agenesis and severe bilateral hypoplasia with cup size less than A, or malformation syndrome (tuberous breast and Poland syndrome);
- QEMA006: Breast reconstruction with insertion of prosthetic implant
Indication: therapeutic. Cosmetic procedures cannot be billed;
- QEMA008: Breast reconstruction using myocutaneous pedicle flap involving muscles other than rectus abdominis
Breast reconstruction using myocutaneous pedicle flap involving latissimus dorsi muscle with or without insertion of prosthetic implant;
- QEKA001: Change of prosthetic breast implant, with capsulectomy
Indication: repair surgery: repeat breast reconstruction (cancer, major asymmetry). If the initial prosthesis insertion was not done for cosmetic purposes;
- QEKA002: Change of prosthetic breast implant, without capsulectomy
Indication: repair surgery: repeat breast reconstruction (cancer, major asymmetry). If the initial prosthesis insertion was not done for cosmetic purposes.

Joint technical specifications have been drawn up, which include the requirements of European standard NF EN ISO 14607 on breast implants. The shape, filling and cover

texture of reimbursed implants have also been specified, and reimbursement is limited to implants containing saline and/or silicone gel.
Conditions for prescription and use have been laid down, so that implants can be reimbursed under the same conditions as those stated in the joint classification of medical procedures (CCAM).

CEPP Opinion

This project has updated device categories, based on new data from the literature and on clinical practice.
The CEPP has examined the working group's proposals. It has adopted the working group's conclusions and issued an opinion on 26 May 2009 concerning those external breast prostheses, tissue expanders and breast implants that are to be reimbursed. Implants used for cosmetic surgery are not recommended for reimbursement by the French national health insurance.