CONSULTATION PHASE FOLLOWING REASSESSMENT OF A CATEGORY OF MEDICAL DEVICES

Hip implants

Summary

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Consultation phase following reassessment of a category of medical devices

The scientific evidence for this assessment can be downloaded from www.has-sante.fr

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Summary

Background

The role of the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) includes providing an opinion on the reimbursement of medical devices for individual use.

Following the decree of 25 July 2005, the Committee for the Assessment of Products and Services (which became CNEDiMTS in September 2009) undertook a technological assessment of hip implants. This assessment led to an opinion being published in September 2007. For each category of hip implant, the Committee gave its opinion, within the context of its remit, on actual benefit (AB), indications it recommends for coverage, minimum technical specifications which characterise the products listed under generic descriptions and on which depends their actual benefit, and conditions for prescribing and use. This assessment work led the Committee to recommend a new nomenclature for the list of products and services qualifying for reimbursement (LPPR), specifying how each category of hip implant should be included (under a generic description or brand name). Where inclusion under brand name is recommended, as well as for any new implant that does not meet the recommended technical specifications for generic descriptions, the company must submit an application reporting the clinical studies conducted on the medical device in question, so that a specific assessment can be undertaken before reimbursement by National Health Insurance is considered.

In particular, the Committee recommended that some implants which were previously reimbursed under broad generic descriptions, and for which specific clinical data were needed, should be listed under brand name. These were the following implants:

- dual mobility cups
- alumina matrix composite ceramic implants (or composite ceramic implants)
- stems with a modular neck.

For these three categories of implant, the Committee gave details of the clinical data required to assess their expected benefit.

A new proposed nomenclature, implementing the Committee’s recommendations, was published in the Official Gazette in 2013 after economic negotiations were undertaken by the Committee for the Pricing of Healthcare Products (CEPS). This publication opened the consultation phase with the manufacturers and healthcare professionals concerned. Their comments mainly related to the following nomenclature issues:

- implants being included on the LPPR according to their type of bearing surface
- dual mobility cups
- composite ceramic implants
- stems with a modular neck
- highly cross-linked polyethylene acetabular implants.
Objective

The objective of this consultation phase is to respond to the comments that were submitted to the CNEDiMTS after the proposed nomenclature was published in the Official Gazette.

At the end of the consultation phase, the CNEDiMTS recommendations are sent to CEPS so it can establish the definitive nomenclature and pricing, which will then be published in the Official Gazette.

Working method

The method chosen for this consultation phase involved:

- analysing the data submitted by manufacturers and professionals;
- updating the literature analysis for the following four topics: dual mobility cups, composite ceramic implants, highly cross-linked polyethylene acetabular implants, and stems with a modular neck;
- gathering the views of experts who met in a multidisciplinary working group which then gave an opinion based on all observations collected;
- consulting stakeholders before the CNEDiMTS examination.

Assessment – Analysis of the data

The Committee noted that the majority of comments submitted by stakeholders were not accompanied by much supporting evidence. A literature analysis was therefore conducted for the topics concerned by these comments.

A total of 643 bibliographic references were identified from a systematic MEDLINE search, and 63 of these were selected on the basis of their abstracts. After analysis, 25 references were retained.

Of the national arthroplasty registries, only the 2013 report from the Australian registry was selected because it reported a comparative analysis of the survival of highly cross-linked polyethylene components versus conventional polyethylene components, together with survival data for hip implants with modular-neck femoral stems versus implants with fixed-neck stems.

- Dual mobility cups

Sixteen studies were selected (n=8441 hips in total, with a mean follow-up of 2 to 22 years): 10 on dual mobility cups used during first-line total hip arthroplasty (1 retrospective comparative study and 9 case series, n=7677 hips) and 6 non-comparative case series on dual mobility cups used during revision total hip arthroplasty (n=764 hips).

The level of evidence for studies on dual mobility cups is low. There is no registry and the only comparative study is retrospective. Many patients were lost to follow-up by the end of the observation period, which makes the results difficult to interpret.

These studies report implant survival data through the event “revision for any reason”.

- The survival rate of hip implants with a dual mobility cup used during first-line arthroplasty is 93% to 95% at 10 years, 89% at 15 years and 74% at 22 years.
- The survival rate of hip implants with a dual mobility cup used during revision arthroplasty for recurrent luxation is 89% to 94.5% at 4 years and 92.6% at 8 years.

The luxation rates reported are variable; they range from 0% to 5.2% for dual mobility cups implanted as a first-line treatment and 0% to 5.6% for dual mobility cups implanted during revision.
No conclusions on the benefit of dual mobility cups can be drawn from these data, mainly because of their poor methodological quality. The diverse range of implant designs and fixation methods may be associated with different implant survival rates.

- **Alumina matrix composite ceramic implants**

  The two randomised controlled trials selected compare composite ceramic-on-composite ceramic bearings to composite ceramic-on-highly cross-linked polyethylene.

  The available data on alumina matrix composite ceramic are limited (n=360 patients in total, mean follow-up less than 3 years). These report a low short-term revision rate (2½ years - 3 years post-surgery).

  No conclusions on the long-term benefit of composite ceramic components can be drawn from these data.

- **Highly cross-linked polyethylene acetabular implants**

  The 2013 report from the Australian arthroplasty registry and a meta-analysis were selected. This meta-analysis included 12 randomised controlled trials comparing total hip replacements (THRs) with a highly cross-linked polyethylene acetabular component (n=513) to THRs with a conventional polyethylene acetabular component (n=525); the mean duration of follow-up ranged from 2.3 years to 8 years.

  The data from the Australian registry favour hip implants with a highly cross-linked polyethylene acetabular component used during first-line hip arthroplasty: this registry reports 12-year revision rates of 5.3% [5.0-5.7] for implants with a highly cross-linked polyethylene acetabular component and 10.1% [9.4-10.9] for implants with a conventional polyethylene acetabular component. A total of 132,128 highly cross-linked polyethylene acetabular implants have been implanted in Australia and 3542 were revised at 12 years.

  The meta-analysis on THRs with a highly cross-linked polyethylene acetabular component used during first-line hip arthroplasty did not demonstrate superiority to THRs with a conventional polyethylene acetabular component in terms of survival, primarily because the follow-up period available from the studies included in this meta-analysis was too short.

  In terms of implant wear, these data are in favour of THRs with a highly cross-linked polyethylene acetabular component over THRs with a conventional polyethylene acetabular component.

  Nonetheless, the very wide range of manufacturing methods must be taken into account and specific long-term data on each implant should be provided.

- **Stems with a modular neck**

  Two retrospective comparative studies, three case series and the 2013 report from the Australian arthroplasty registry were selected.

  The registry cites a higher revision rate for THRs with a modular neck than for THRs with a fixed neck after a 10-year follow-up period (10.8% [9.6; 12.1] for hip implants with a modular neck vs. 6.4% [6.3; 6.6] for those with a fixed neck). A total of 8971 stems with a modular neck have been implanted in Australia and 544 were revised at 10 years.

  In addition, the data available in the literature on stems with modular necks used during first-line hip arthroplasty or during revisions are limited (1000 patients included in total, follow-up period less than 10 years, studies with a poor methodological quality).

  No conclusions on the benefit of stems with a modular neck can be drawn from these data.
Working group opinion

The working group has given its opinion regarding the conclusions from the critical analysis of the literature, as well as the issues raised by this consultation phase that did not require a literature analysis.

- **Standard bearing surface**

  According to the group, metal-on-conventional polyethylene remains the standard bearing surface to be used when comparing materials. This bearing surface has been implanted for over 30 years and has a 30-year survival rate of about 80%.

- **Listing by bearing surface**

  The working group considers that each component should be listed separately on the LPPR to avoid a product coming under 2 different generic descriptions depending on whether it is used as a bearing surface in a first-line total hip arthroplasty or as a unit component during a revision.

  The working group proposed updating the nomenclature based on the principle that one implant = one LPPR code.

- **Dual mobility cups**

  The working group recognised the value of the dual mobility concept and its practical interest while emphasising the diverse range of implant designs and fixation methods, which are associated with different failure rates.

  The group considers that the published studies cannot address the uncertainties about the survival of this type of implant, particularly because of the large number of patients lost to follow-up. In addition, because of the diverse range of implant designs, minimum technical specifications cannot be defined.

  The group confirmed the indications for this type of implant, namely first-line arthroplasty in patients with a very high risk of luxation (severe neurological conditions, neuropsychiatric disorders, addictions and significant neuromuscular diseases), and revision arthroplasty in cases of recurrent luxation, as well as revision arthroplasty with a high risk of luxation.

  The preferred fixation method was also specified.

- **Composite ceramic implants**

  The BIOLOX DELTA implants manufactured by CeramTec are the only alumina matrix composite ceramic implants available in France since January 2013.

  The group considers that the available data on the short-term survival of composite ceramic implants are reassuring. However, there are no data on the long-term survival of composite ceramic implants.

  Since composite ceramic implants are made by the same manufacturer, the group recommends inclusion under a generic description. This should consist of composite ceramic implants complying with the international standard ISO 6474-2:2012.

  Nonetheless, long-term survival data are needed.

- **Highly cross-linked polyethylene acetabular implants**

  Several highly cross-linked polyethylene acetabular implants are listed under brand name on the LPPR. Given the diverse range of manufacturing methods identified, the group confirms the need to list highly cross-linked polyethylene under brand name.
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- **Stems with a modular neck**
  
The results from the Australian registry are not in favour of stems with a modular neck. There are no long-term data. Therefore, the group confirms the Committee's recommendations and considers that this type of implant should be included under brand name.

The clinical data required concern implant survival and luxation at a minimum.

- **Age limit**
  
According to the working group, an individual's physical activity levels take precedence over age when defining the indication for highly cross-linked polyethylene and ceramic-on-ceramic implants. The group takes into account that these implants are indicated in independent and active individuals who have a Parker score greater than 6 and no major comorbidities.

The maximum age limit is set at 70 years. The group is in favour of extending this limit to 75 years while considering that the age criterion is simply a guide, as physical activity levels in the 70-75 year group vary widely.

- **Technical specifications**
  
The group gave its opinion on the comments regarding technical specifications (revision stem length, femoral head diameter, minimum thickness of conventional polyethylene, stem roughness, etc.).

- **Clinical data expected**
  
Listing under brand name involves a specific assessment of each implant. Some of the comments submitted concerned the difficulties of implementing, in accordance with the requirements expressed by the Committee in its 2007 opinion (as regards study type and endpoints), the clinical studies which are mandatory to evaluate the individual benefit of hip implants, with a view to inclusion under brand name. The working group proposes the following clarifications in response to these comments.

The working group considers that a randomised controlled trial can be successfully set up if randomisation is stratified by centre, so that the usual practices of each centre can be taken into account, and provided clinical outcomes are assessed by an independent assessor.

According to the group, a more relevant endpoint than cup migration or measuring displacement of a femoral component at 2 years is the migration kinetics of components up to 2 years post-surgery, with an aim of stabilisation at 3-6 months post-surgery. Validated measurement methods such as EBRA and highly sensitive measuring tools are available.

The group emphasises that joint implant survival is an insufficient endpoint for evaluating the benefit of hip implants. Data on the luxation rate and the morbidity of revisions should also be taken into account.

In addition, independently of any specific application for inclusion under brand name, long-term clinical data are still needed in the context of the French healthcare system. The working group would like good-quality follow-up data to be available from a French registry and/or extracted from National Health Insurance databases.
General Conclusion of the National Committee for the Evaluation of Medical Devices and Health Technologies

The CNEDIMTS recommends:

- separating out each joint component that is used in a bearing surface and giving it a specific LPPR code;
- continuing to include dual mobility cups, highly cross-linked polyethylene acetabular implants and stems with a modular neck under brand name;
- creating two generic descriptions for implants made from solid alumina matrix composite ceramic (femoral heads and liners), to be added to the descriptions for implants made from pure solid alumina ceramic;
- removing the generic descriptions for monoblock revision stems and revising the generic descriptions for revision stems and reconstruction stems, with the creation of eight generic descriptions based on level of modularity and fixation method;
- maintaining the minimum thickness requirement for conventional polyethylene at 8 mm when it is in contact with a metal head (for acetabular components and intermediate cups with an external diameter ≥ 44 mm), while leaving the possibility for reducing the minimum thickness requirement to 6 mm to meet the anatomical constraints of acetabular components and intermediate cups with an external diameter < 44 mm, needed in restricted anatomical situations (i.e. in 5% to 10% of cases);
- maintaining the requirement for cemented stems to have a roughness (arithmnetic roughness) < 1.26 µm;
- extending the indications for hip implants in traumatology to some fractures of the upper extremity of the femur (cervicotrochanteric and trochanteric fractures) where hip arthroplasty may be an alternative to the conventional treatment with osteosynthesis.

In addition, the Committee maintains its requirements for the clinical studies needed to support application for inclusion under brand name of a hip implant on the list of products and services qualifying for reimbursement.

Where comparative data are necessary, the Committee considers that a randomised controlled trial is the most appropriate tool for evaluation. The Committee points out that it is possible to take the usual practices of each centre into account if randomisation is stratified by centre. In addition, using an independent assessor allows measurement bias to be avoided.

The Committee accepts the working group’s proposals regarding the clinical trial endpoints expected.
Contributors

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The members of the working group were appointed by the CNEDiMTS board from among experts recommended by French professional bodies in the relevant medical fields, experts who responded to the call for applications, and experts known to HAS.

In accordance with Decree 2004-1139 of 26 October 2004 (articles R. 161-84 to R. 161-86 of the Social Security Code), all members of the working group completed a declaration of interests, indicating any direct or indirect links with companies or organisations involved in the field in which HAS operates. These declarations of interest have been published on the HAS website.

The declarations of interest were analysed in accordance with the criteria in the HAS Guide des déclarations d'intérêts et de gestion des conflits d'intérêts [Guide to Declarations of Interest and Management of Conflicts of Interest] (adopted by the HAS Board on 24 July 2013). A summary table of interests declared was examined by the CNEDiMTS Board, which decided on the final composition of the working group. The interests declared by the experts that were accepted by the CNEDiMTS board were all considered to be “non-significant”.

The table summarising the interests declared was made public and, where applicable, updated from the up-to-date declarations of interest made by the experts at the start of the working group meeting and on presentation of the working group’s opinion to CNEDiMTS.