RAPID ASSESSMENT METHOD FOR ASSESSING MEDICAL AND SURGICAL PROCEDURES

The opinions issued by the Haute Autorité de santé (HAS) contain a statement on the benefit provided by the procedure under assessment. This covers:
- the diagnostic or therapeutic benefit, based on safety, efficacy, and contribution to the treatment strategy;
- the public health benefit, based on impact on the morbidity and mortality related to the disorder treated, on patients' quality of life, on the care system, and on public health policies and programmes. Public health benefit also depends on the severity of the disorder treated and on whether the procedure meets an unsatisfied need.

The method used by HAS to deliver this opinion consists of:
- an analysis of identified published data on the factors listed above;
- the issuing of an opinion on those factors, by a working group of professionals.

All the work is coordinated by a HAS project manager who ensures that it complies with HAS methodology.

1. Literature search and analysis of scientific data

The in depth literature search consists in the following steps:
- a focused search of medical and scientific literature databases for a period appropriate to each topic. A stage common to all studies is a systematic search for existing published national and international clinical practice guidelines, consensus conferences, systematic reviews, meta-analyses and other assessments;
- consultation of relevant websites (government agencies, learned societies etc.);
- a search for documents in the grey literature and for relevant legislative and regulatory texts.

Articles may be in French or English. All searches are updated until the end of the project. Each article selected is reviewed according to the principles of critical appraisal of the literature using checklists. A level of scientific evidence (HAS grading scheme) is allocated to each study.

<table>
<thead>
<tr>
<th>Level of scientific evidence (Levels I to IV)</th>
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<tbody>
<tr>
<td>I- High powered randomised controlled trials, meta-analyses, decision analyses.</td>
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<tr>
<td>II- Low powered randomised controlled trials, or non-randomised trials, cohort studies.</td>
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<td>III- Case-control studies.</td>
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<td>IV- Retrospective studies, case series, descriptive epidemiological studies, and controlled trials with bias.</td>
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2. Writing the draft report

The HAS project manager selects, reviews and summarises the relevant medical (and if appropriate, economic) published data, and produces a draft report, with the assistance of external report authors if necessary.

1 According to article R162-52-1 of the Social Security Code.
3. Consulting the working group

A working group is formed after consultation with learned societies concerned by the topic. It consists of health professionals from a number of disciplines, working in different types of public or private practice from all over the country and from all schools of thought. The group meets once. Group members receive the literature review together with a questionnaire asking for their opinion before the meeting. At the meeting, they discuss whether the literature review and their own experience meet the criteria used to measure the procedure's clinical benefit (see above) and, if possible, reach a consensus. The HAS project manager produces a report of the meeting (discussion and final opinion) and submits it to the working group members.

4. Report validation and opinion of the HAS Board

The HAS Committee for Assessment of Medical and Surgical procedures estimates the benefit of the procedure in the light of the literature review and the opinion of the working group, examines and validates the report.

HAS' Board issues then an opinion on whether the procedure should be included on the list of procedures reimbursed by National Health Insurance. They have three options:

<table>
<thead>
<tr>
<th>Clinical benefit</th>
<th>HAS' opinion on inclusion</th>
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<tbody>
<tr>
<td>Sufficient</td>
<td>Approved</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Not approved</td>
</tr>
<tr>
<td>Cannot be estimated</td>
<td>Procedure still in clinical research phase</td>
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In addition to estimating the clinical benefit of the procedure, the HAS opinion also specifies:
- the indication for the procedure,
- its contribution to the diagnostic or treatment strategy,
- the improvement in clinical benefit of the procedure compared with alternatives,
- an estimate of the number of patients who will potentially benefit from the procedure,
- an assessment of procedures for implementation and quality and safety requirements,
- the degree of severity of the disease or condition,
- if necessary, the aim of further studies to refine assessment of the clinical benefit of the procedure.

5. Publication

HAS makes the summary and the complete report available online free of charge on its website (www.has-sante.fr). An English translation of the summary is available on the HAS and INAHTA websites (www.inahta.org).

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2 According to article R162-52-1 of the Social Security Code
3 INAHTA: International Network of Agencies for Health Technology Assessment