HTA pricing and reimbursement in France: What changes? Which consequences?

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June 2015
From HTA to reimbursement

Appraisal Committee Guidance

HTA

Decision making

Drugs

Medical Devices

CEPS
Economic Committee for Healthcare Products

Procedures

UNCAM
Nat. Health Insurance Union

Public Health Interventions (Screening programmes...)

Ministry of Health, M. of Social Security

HTA Decision making
• Creation of a Positive list for reimbursed drugs

• A new drug will be reimbursed only if it has shown efficacy and either have improved clinical outcomes or have similar outcomes but induce savings.

• Committee set up to evaluate drugs

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MINISTÈRE DES AFFAIRES SOCIALES

Décret n° 67-441 du 5 juin 1967 relatif aux conditions de remboursement des médicaments aux assurés sociaux.

Le Premier ministre,

Sur le rapport du ministre des affaires sociales, du ministre de l’économie et des finances et du ministre de l’industrie,

Vu le code de la sécurité sociale, et notamment les articles L. 249 et suivants;

Vu le code de la santé publique, et notamment les titres II et IV du livre V;

Vu l’article 63 du décret n° 60-452 du 12 mai 1960;

Vu l’avis du conseil interministériel de coordination en matière de sécurité sociale;

Le Conseil d’État (section sociale) entendu,

Décèrte:

Art. 2. — Les médicaments auxquels s’applique l’article L. 601 du code de la santé publique ne peuvent être remboursés ou pris en charge par les organismes de sécurité sociale, sur prescription médicale, ni être achetés ou fournis ou utilisés par eux que s’ils figurent sur une liste des médicaments remboursables établie par arrêté du ministre des affaires sociales.

Art. 3. — Ne peuvent être inscrits sur la liste prévue à l’article 2 que les médicaments qui présentent une efficacité et qui sont présumés apporter une amélioration de la thérapeutique ou une économie dans le coût du traitement. A efficacité ou économie comparable, préférence est donnée aux médicaments qui résultent d’un effort de recherche du fabricant.
Clinical aspects
- clinical efficacy
- clinical effectiveness
- relative effectiveness

Other aspects
- disease characteristics
- target population
- impact on public health
- impact on healthcare organisation (qualitative)

Actual Benefit
- Insufficient
- Sufficient

Clinical added value
- No CAV(V)
- Minor CAV (IV)
- High to moderate CAV(I,II,III)

Results
- No reimbursement
- Reimbursement only if price inferior to comparators
- Price may be higher than comparators
- European Price

Decision: Ministry Pricing:
Economic Committee
Evolution of the French system

Determination of added clinical benefit

Price negotiation and decision

Towards a new criterion?

Introduction of economic evaluation to inform decision on price
Rules governing price setting

• **Primary considerations when setting prices:**
  – added clinical benefit (ASMR),
  – prices of comparators,
  – forecast sales volumes (clawback payments in case of overshooting)

• **Link between ASMR and price**
  – drugs that provide no added clinical benefit (ASMR 5) as assessed by HAS and no savings on treatment costs cannot be reimbursed
  – Drugs with ASMR 1-3: the price is not inferior to the lowest price in 4 European countries
The role of HAS

– To inform the public decision-maker of any disproportion between the cost differential and the effectiveness differential between comparable interventions (technologies)

▶ Foster the acquisition of knowledge on the economic issues associated with the inclusion of an intervention in the basket of goods and services

▶ Stimulate public debate on the level of resources that society is prepared to devote to health

▶ Encourage the identification of collective values as a basis for agreement on public health priorities
Regulatory and organisational context
Laws and regulations

• Law of 2004 creating HAS
• Social Security Financing Act for 2008 (LFSS)
• Social Security Financing Act for 2012 (LFSS)
• Implementing decree of 2 October 2013
HTA Division organisational chart

Medical, Economic and Public Health Assessment Division
Jean Patrick Sales
Deputy: Catherine Rumeau Pichon

Medicines

Economics and Public Health
Catherine Rumeau Pichon
Deputy:
Anne d’Andon
Deputies:
Emmanuelle Cohn
Caroline Tranche

Dx and Tx Procedures
Michèle Morin Surroca
Deputies:
Denis Jean David
Marc Guerrier

Medical Devices
Catherine Denis
Deputies:
Corinne Collignon
Hubert Galmiche

Methodology and Epidemiology Unit

Transparency Committee

Economics and Public Health Committee

MDs and Technologies Committee
Article 47 of the 2012 LFSS: economic evaluation of healthcare products
Coordinated appraisal – Opinion of each Committee – sent to the CEPS

HAS specialist committees
Decision maker for pricing

Health economic assessment
Medical assessment

CEESP
CNEDIMTS CT

CEPS Pricing Committee
The 2012 LFSS: The impact on HAS’ health economics mission

• Article 47 of the 2012 LFSS establishes a “specialist” committee with regulatory status for HAS’ health economic studies

• HAS is responsible for its composition

• The HAS Board has used a composition similar to that of the previous CEESP (without deputies):
  – 1/3 economists
  – 1/3 representatives of other human and social science disciplines (sociology, law, philosophy, geography, management, political sciences) and users/consumers
  – 1/3 members with medical training (4 public health doctors, 3 epidemiologists, 2 GPs, 1 surgeon, 1 nursing officer, 1 gerontologist, 1 psychiatrist, 1 gastroenterologist)
Which products should be analysed for cost-effectiveness?

The decree:

1. *the recognition or confirmation of a major, important or moderate improvement in actual clinical benefit or expected clinical benefit [...] is sought by the company*

2. *the product or the technology has or is likely to have a significant impact on National Health Insurance expenditure given its effect on the organisation of care, professional practices or the conditions of patient care and, if applicable, its price.*
Which products should be analysed for cost-effectiveness?

The concept of “significant impact”

- Decision of the HAS Board of 18 September 2013
- The manufacturer claims an impact on:
  - The organisation of the care system,
  - Professional practices
  - Patient treatment methods
- In the absence of a claim, the Board considers that an assessment of cost-effectiveness is required if the projected turnover (2 years from launch, for the full year) > €20 million inclusive of tax
- If not, the Board assesses whether an economic evaluation is appropriate in the light of the manufacturer’s claims.
Which products should be analysed for cost-effectiveness?

• The HAS Board considers that an economic evaluation is not required:
  – If a conventional price-cutting procedure has begun
  – If the product’s patent is in the public domain

• The HAS Board considers that the recorded turnover is taken into account across all indications
Who is it for?

The decree

“The final opinion is communicated to the company with copy to the Healthcare Products Pricing Committee (CEPS). It is made public.”

• The opinion on cost-effectiveness is intended primarily for the CEPS, with a view to negotiating the price
• Can products approved for hospital use, not included in the “additional list”, be used by hospital purchasers?
• Opinions on cost-effectiveness are published on the HAS website
Article 4: the contractual framework between Pharma industry association and CEPS

“...in the case of medicines for which an IACB level I to III has been applied and obtained and which have received a health economic opinion from the CEESP, issued within the statutory timeframes, enabling the CEPS to establish the conditions of their cost-effectiveness, agreements ensure that the price will not be lower than the lowest price charged on the 4 main European markets...”
• “In order to encourage the actual inclusion of the health economics assessment in price setting […]”

• “You will emphasise the use of the health economic assessment by applying to the competent HAS committee for an opinion whenever you consider it necessary.”

• “The committee will endeavour to ensure that product reimbursement is cost-effective […]”
Which methods?

The decree

“The opinion is based on a comparative analysis, between the various medically relevant treatment alternatives, of the costs incurred relative to the expected or observed benefits for the health and quality of life of the persons concerned.”


2. Early consultation is facilitated.
A METHODOLOGICAL GUIDE

Choices in Methods for Economic Evaluation

October 2012

Department of Economics and Public Health Assessment
Organisation: 11 stages – 90 days

Early consultation
1. Submission by the manufacturer
2. Administrative admissibility
3. Scientific/methodological admissibility
4. HAS internal analysis + sub-committee rapporteur
5. Additional technical/methodological questions
6. Writing the draft opinion
7. Economic sub-committee
8. CEESP validation
9. Sending to the manufacturer
10. Discussion stage
11. Final opinion published
In practice

1. **Submission of the form justifying the significant impact**
   - In all cases
   - Cost-effectiveness dossier compulsory > €20 million
   - Significant impact to be argued

2. **Submission of the cost-effectiveness dossier to the CEESP**
   - Avis_efficience@has-sante.fr

3. **Request for early meetings**
   - Avis_efficience@has-sante.fr
   - Specific dossier
Form and content of opinions on cost-effectiveness
Admissibility

1. Admissibility: an essential prerequisite
2. A single criterion: the study design does not allow the cost-effectiveness to be documented
   - Objective criterion, indisputable and easily identified
   - Examples:
     - Budgetary impact studies, without prior demonstration of the product’s cost-effectiveness
     - Non-comparative studies
     - Costings without comparison with health benefits obtained from the intervention

3. In the event of inadmissibility
   - The critical examination of the method is not conducted
   - The opinion is limited to the inadmissible nature of the study performed to assess the cost-effectiveness of the healthcare product.

4. Conclusion ➔ “negative” opinion
Methodological compliance

- **Objectives:**
  - To validate the method of demonstrating cost-effectiveness
  - To identify the level of uncertainty associated with the results presented by the applicant

- **The CEESP considers 5 scenarios:**
  1. The method is fully compliant
  2. The method is acceptable with low uncertainty ➔ minor reservations
  3. The method is acceptable despite high uncertainty ➔ significant reservations
  4. The method is non-compliant, invalid study ➔ major reservations
  5. The study method is considered insufficiently documented ➔ compliance not characterised
Conclusion in terms of cost-effectiveness

1. In the event of methodological non-compliance, in the conclusion:
   - No quantitative result is included
   - The non-compliant nature of the study is referred to
   - It is made clear that cost-effectiveness is not demonstrated

2. When the study method is acceptable, the conclusion specifies:
   - The nature of the methodological reservations
   - The degree of uncertainty characterising the quantitative results
   - The incremental cost-effectiveness ratio or the mean net benefit (no reference to a threshold)
   - The price set
   - Any elements to be taken into account based on the results
Additional data

This part has two objectives:

– To guide future studies so as to reduce the uncertainty associated with the results:
  → Relating to data not yet available (uncertain parameters or non-validated hypotheses).
  → Relating to questions not considered in the initial assessment (for example, analysis in a particular population).

– To guide the collection of data so that the cost-effectiveness, once established, can be documented.
December 2014 review
97 dossiers received at the SEESP

- 19 dossiers not covered by the decree before referral to the Board

- 78 dossiers were examined for eligibility by the Board
  - 52 dossiers not eligible for health economic assessment (*no significant impact found by the HAS Board*)
  - 26 dossiers eligible for health economic assessment (*significant impact found by the HAS Board*)
Board decisions on eligibility

Medicines: 52
- Eligible for health economic assessment: 25
- Not eligible for health economic assessment: 27

Medical devices: 26
- Eligible for health economic assessment: 1
- Not eligible for health economic assessment: 25
Opinions delivered

- Dossiers closed: 15
- Mean time for review: 115 days
- Dossiers with technical exchange: 15
  - Mean suspension time during technical exchange: 23 days
  - Technical meetings: 4
- Dossiers with discussion stage: 14
  - Hearings: 6
  - Observations without a hearing: 8
Final opinions (on 31/12/14)

- Defibrotide (Defitelio®)
- Radium dichloride (Xofigo®)
- Panitumumab (Vectibix®)
- Riociguat (Adempas®)
- Trastuzumab emtansine (Kadcyla®)*
- Lemtrada®*
- Herpes zoster vaccine (Zostavax®)
- Rotavirus vaccine (Rotateq®)
- Rotavirus vaccine (Rotarix®)
- Tecfidera®
- Simeprevir (Olysio®)
- Sofosbuvir (Sovaldi®)*
- Dolutegravir (Tivicay®*)
- Botulinum toxin (Botox®)
- Macitentan (Opsumit®)
- Xolair®
- Vedolizumab (Entyvio®)

*opinions published on the website.
Opinions pending

**Medicines**
- Pirfenidone (Esbriet®)
- Obinutuzumab (Gazyvaro®)
- Daclatasvir (Daklinza®)
- Fluenz Tetra
- Romiplostim (Nplate)
- Ledipasvir+sofosbuvir (Harvoni®)
- Idelalisib (Zydelig®)
- Imbruvica

- Xtandi
- Ombitasvire +paritaprevir +ritonavir (Viekirax®)
- Dasabuvir (Exviera®)

**Medical devices**
- Mitraclip®
Early meetings: some figures

From June 2013 to December 2014:
42 early meetings held
15 dossiers submitted to the SEESP

Subjects addressed:
- Comparator (+++): all dossiers
- Importance of assessing the impact of uncertainty on the ICER (++)
- The timeframe
- The population analysed
- Utility data
- Direct costs to be taken into account
What use of HE in France in the frame of rapid HTA?

1. **Product price (decided by the company)**
   - ICER Cost/QALY
   - Comparison to threshold
   - Decision on reimbursement taken by NICE

2. **Product price (proposed by the company)**
   - ICER Cost/QALY
   - HAS gives advice
   - Price decided by Pricing Committee
Evolution of the French system

Determination of added clinical benefit

Price negotiation and decision

Towards a new criterion?

Introduction of economic evaluation to inform decision on price
Dans un délai de 18 mois à compter de la promulgation de la présente loi, le Gouvernement est autorisé à prendre par ordonnance toutes mesures relevant du domaine de la loi afin :

1. De faire évoluer les conditions de l'évaluation des médicaments et des dispositifs médicaux, en adaptant notamment les compétences et la composition des commissions concernées ;

2. D'adapter la gouvernance de la HAS, les modalités d'exercice de ses missions ainsi que la composition de son collège.
From HTA to pricing and reimbursement

**ASSESSMENT**
- Literature
- Dossier from Pharmaceutical Company
- HAS internal assessors
- Review of available data

**APPRAISAL**
- HAS Specialist Committee
- HAS Guidance

**Decision making body**
- Reimbursement Pricing

Request for additional data collection

Decision on P&R
From HTA to pricing and reimbursement

- Dossier from Pharmaceutical Company
- Literature

**ASSESSMENT**
- HAS internal assessors
- Review of available data

**APPRAISAL**
- HAS Specialist Committee
- HAS Guidance

**Decision making body**
- Reimbursement Pricing
- Decision on P&R

Request for additional data collection
Cooperation on HTA production

**ASSSESSMENT**
- HAS internal assessors
- Review of available data

**APPRAISAL**
- HAS Specialist Committee
- HAS Guidance

**Decision makers on reimbursement and Price**
- Decision on P&R
- Request for additional data collection

**Joint Assessment (Core HTA)**

**Methodological Guidelines**

**Dossier from Pharmaceutical Company**

**Literature**
Improvement of quality of data produced

- Literature
- Dossier from Pharmaceutical Company

ASSESSMENT
- HAS internal assessors
- Review of available data

APPRAISAL
- HAS Specialist Committee
- HAS Guidance

Decision makers on reimbursement and Price
- Decision on P&R
- Request for additional data collection
- Additional data collection

Early Dialogue
Brief ED Overview: EUnetHTA & SEED

- **JA1**
  - 2 preparatory early dialogues
  - ED procedure drafted for JA2

- **JA2**
  - Draft ED procedure in JA1 used for 8 ED pilots
  - ED survey conducted after first 6 ED pilots
  - Refined ED procedure produced following WP7 FtF meeting (Jan’14) based on discussion (taking into account survey results)

- **SEED**
  - Revised JA2 EUnetHTA ED procedure used as the basis for SEED
  - ED procedure further amended (Nov’14) and progressively introduced with SEED’s 8th ED
  - Conducted 9 EDs to date (6 drugs / 3 medical devices)
  - 10th ED planned in March; additional 11th ED planned in June

- **JA2**
  - 1 ED ongoing (medical device in heart disease)
  - 2 additional EDs budgeted; June and Sept 2015
Update on collaborative HTA early dialogues

- Total number of early dialogues: 24 instead of the 4 initially planned in 2012
  - EUnetHTA:
    2 on Medical Devices
    11 on drugs (no parallel with EMA, but EMA observer in some)
  - SEED:
    3 on Medical Devices
    8 on drugs (4 HTA only, 4 parallel EMA-SEED)
- Recommendations for permanent model for conducting early dialogues (ED) to be produced by SEED, in cooperation with EUnetHTA
SEED outputs

- 10 (+1) Early Dialogues
  - Confidential part

- 10 (+1) reports on each ED (procedural aspects)
  - Non confidential part

- Report to propose permanent model
  for Early Dialogues in Europe
  - To be delivered to the European Commission by End 2015
Thank you for your attention

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