France has a centralised pricing and reimbursement system, with a substantial amount of influence held by the Transparency Commission of the Haute Autorité de Santé, although public and private insurers are also involved in pricing decisions.

Reimbursement of effective drugs is generous, however there are large patient copayments (often covered by complimentary insurance) for ambulatory treatments that are less effective.
Submit dossier and set initial price request

Submit information

Assessment of dossier

Economic assessment

SMR

Reimbursement

Important: 65% to 100%
Moderate: 30%
Mild: 15%
Insufficient: None

ASMR

Pricing rule

1–3: Negotiated with CEPS, considering EU5 prices
4: At comparator price
5: Lower than comparator price

Possible price negotiation

Price negotiated or set

Agreement and contracting

Reimbursement set and price published

TC considers if a drug should be reimbursed based on its medical benefit (SMR) and if the drug is an improvement compared with existing therapies (ASMR).

CEESP analyse manufacturer’s economic analysis to ensure compliance with HAS guidelines and evaluate the cost per QALY.

Reimbursement is set by UNCAM using the SMR granted by the TC – final listing is approved by the MoH.

The TC does not publish guidance on trial endpoints, comparator or duration, however it does prefer French patients to have been included in the study.

CEPS is made up of many stakeholders including representatives of the MoH, MoF, MoR and insurers (public and private).

CEPS sets price/volume agreements, considering comparator prices as well as 3-year sales forecasts, likely real-world usage and target population size.

SMRs and ASMRs granted in 2016

ASMR=Amélioration du Service Médical Rendu (improvement in medical benefit); CEESP=Commission Évaluation Économique et de Santé Publique; CEPS=Comité Économique des Produits de Santé; HAS=Haute Autorité de Santé; ICER=incremental cost-effectiveness ratio; MoF=Ministry of Finance; MoH=Ministry of Health; MoR=Ministry of Research; QALY=quality-adjusted life-year; SMR=Service Médical Rendu (medical benefit); TC=Transparency Commission; UNCAM=Union Nationale des Caisses d’Assurance Maladie

n=19

Concerns cited by CEESP with manufacturer economic analyses submitted (2011-16)**

SMRs and ASMRs granted in 2016

As shown in the figure, 89% included at least one important and/or major methodological concern.

37% of dossiers were completely invalidated by major concerns.

*Two part submission: a technical file and an economic file, evaluated by the TC and CEESP/CEPS, respectively. **Economic assessment by CEESP if there is likely to be a significant spending impact, or if the manufacturer is seeking an ASMR of 1–3. ***Generally 65% for a typical ambulatory prescription and 100% for a hospital/specialist prescription. Based on efficacy, safety, the position of the medicine in the therapeutic strategy and the availability of therapeutic alternatives.

**REIMBURSEMENT AND PRICING PROCESS**

Submit dossier and set initial price request

- Submit information
  - Assessment of dossier
    - Economic assessment
      - SMR
        - Important: 65% to 100%
        - Moderate: 30%
        - Mild: 15%
        - Insufficient: None
      - ASMR
        - 1–3: Negotiated with CEPS, considering EU5 prices
        - 4: At comparator price
        - 5: Lower than comparator price
      - Possible price negotiation
      - Agreement and contracting

- Reimbursement set and price published
  - Reimbursement is set by UNCAM using the SMR granted by the TC – final listing is approved by the MoH.
  - CEESP analyse manufacturer’s economic analysis to ensure compliance with HAS guidelines and evaluate the cost per QALY.
  - CEPS is made up of many stakeholders including representatives of the MoH, MoF, MoR and insurers (public and private).
  - CEPS sets price/volume agreements, considering comparator prices as well as 3-year sales forecasts, likely real-world usage and target population size.

**KEY CONSIDERATIONS**

TC considers if a drug should be reimbursed based on its medical benefit (SMR) and if the drug is an improvement compared with existing therapies (ASMR).

CEESP analyse manufacturer’s economic analysis to ensure compliance with HAS guidelines and evaluate the cost per QALY.

Reimbursement is set by UNCAM using the SMR granted by the TC – final listing is approved by the MoH.

The TC does not publish guidance on trial endpoints, comparator or duration, however it does prefer French patients to have been included in the study.

**IN PRACTICE**

Concerns cited by CEESP with manufacturer economic analyses submitted (2011-16)**

- Structural choices: 19%
- Study objective: 12%
- Measurement and calculation of health states and costs: 4%
- Results presentation and sensitivity analysis: 19%
- No concerns: 3%

SMRs and ASMRs granted in 2016

- Important: 74%
- Minor: 0%
- Moderate: 26%
- Insufficient: 2%
- ASMR: 19%
- SMR: 74%

**ASMR**=Amélioration du Service Médical Rendu (improvement in medical benefit);

**CEESP**=Commission Évaluation Économique et de Santé Publique; **CEPS**=Comité Économique des Produits de Santé; **HAS**=Haute Autorité de Santé; **ICER**=incremental cost-effectiveness ratio; **MoF**=Ministry of Finance; **MoH**=Ministry of Health; **MoR**=Ministry of Research; **QALY**=quality-adjusted life-year; **SMR**=Service Médical Rendu (medical benefit); **TC**=Transparency Commission; **UNCAM**=Union Nationale des Caisses d’Assurance Maladie

*Two part submission: a technical file and an economic file, evaluated by the TC and CEESP/CEPS, respectively. **Economic assessment by CEESP if there is likely to be a significant spending impact, or if the manufacturer is seeking an ASMR of 1–3.

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