Pricing & Reimbursement in France
France has a centralized 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 complementary insurance) for ambulatory treatments that are less effective.

Key Considerations

- The TC considers if a drug should be reimbursed, based on its medical benefit (SMR) and clinical added value, compared with existing therapies (ASMR).
- The CEESP reviews a 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. Hospital-only drugs with SMR “important” and ASMR I–III ratings are placed on the “liste-en-sus,” (high-cost drugs reimbursed outside the hospital budget), which provides extra financial support by health insurance, in addition to the standard hospitalization rates.

In Practice

Concerns cited by CEESP with manufacturer economic analyses submitted (2011–16)††

- 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.
- The CEPS is made up of many stakeholders, including representatives of the MoH, MoF, MoR and insurers (public and private).
- The CEPS sets price/volume agreements, considering comparator prices— as well as three-year sales forecasts, likely real-world usage and target population size.

Pricing and Reimbursement Process

- Submit dossier* and set initial price request
- Assessment of dossier
- Economic assessment†
- Manufacturer
- TC of HAS
- CEESP
- CEPS
- UNCAM & MoH
- Patient Groups
- Possible step
- 30 days
- 90 days
- 90 days
- 90 days
- 180 days
- 90 days
- 90 days
- Agreement and contracting
- Reimbursement set and price published

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

<table>
<thead>
<tr>
<th>ASMR</th>
<th>Pricing rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–3</td>
<td>Negotiated with CEPS, considering EUS prices</td>
</tr>
<tr>
<td>4</td>
<td>At comparator price</td>
</tr>
<tr>
<td>5</td>
<td>Lower than comparator price</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SMR</th>
<th>SMRs and ASMRs granted in 2019†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important</td>
<td>Oncologics</td>
</tr>
<tr>
<td>Moderate</td>
<td>68%</td>
</tr>
<tr>
<td>Minor</td>
<td>3%</td>
</tr>
<tr>
<td>Insufficient</td>
<td>29%</td>
</tr>
</tbody>
</table>

*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 I–III; 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.

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