

Market access and reimbursement of medical devices in France

April 3d, 2019



ASCAM-DM

ASSOCIATION DES SOCIÉTÉS DE CONSEIL
EN ACCÈS AU MARCHÉ - DISPOSITIFS MÉDICAUX

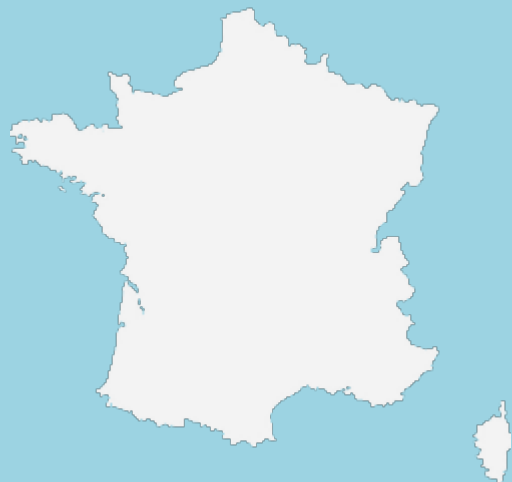
Who we are?



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SUMMARY

1. Overview & process
2. Hospital reimbursement system:
4 ways to reimburse Medical Devices
3. Health Technology Assessment
4. Innovation



French Market Access Overview

Market access in Europe: Key drivers

Innovation-focused
Patient-focused



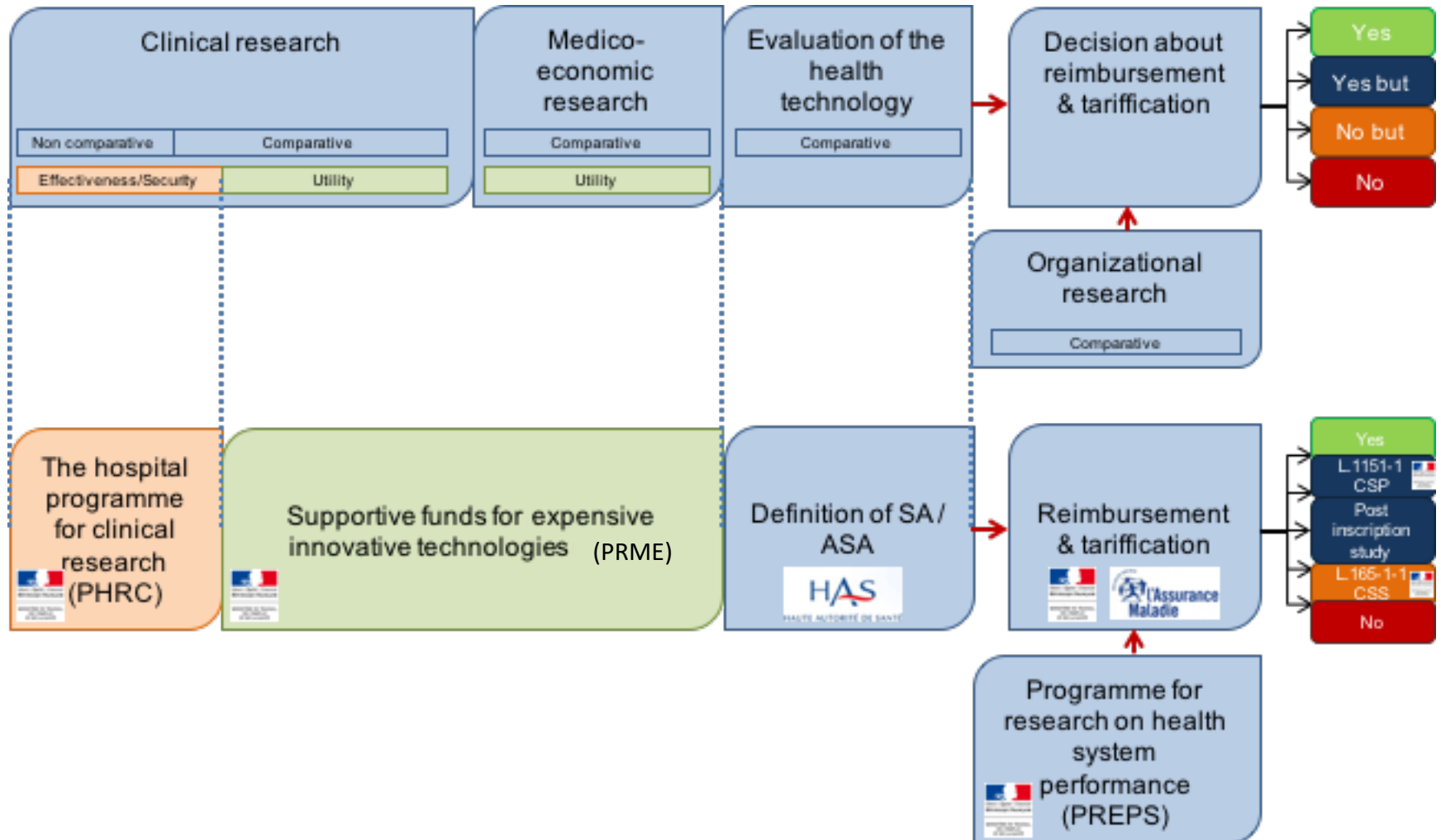
Financial (DRG)



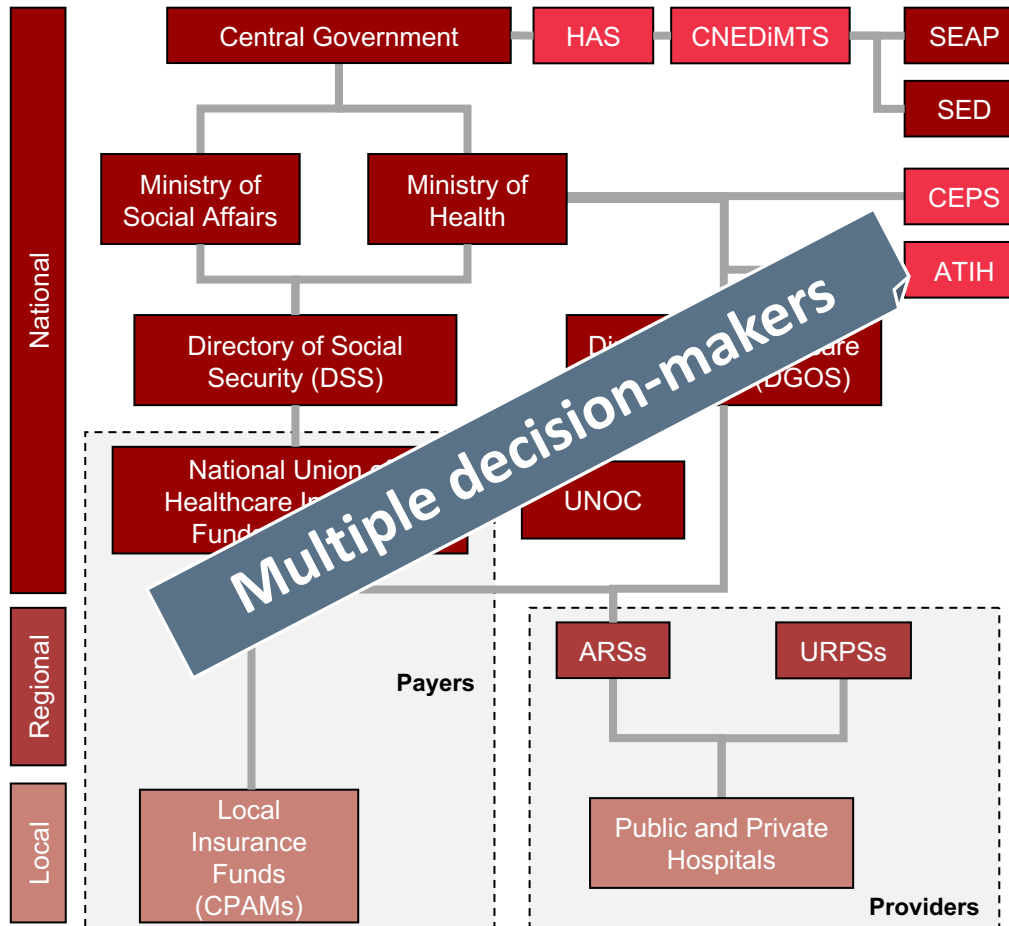
HEOR



Ministry of health: continuum of MD funding



The French Healthcare System: Insurance-Based and Centralized Decision Making System



Ministry of Social Affairs and the Ministry of Health and General fund (covering 85% of the population) includes:

- 26 regional funds (within the ARSs)
- 101 local funds (CPAMs)

HAS - Is the independent national HTA organization – **CNEDiMTS** is the Evaluation Commission for medical devices (SED), diagnostics and therapeutic procedures (SEAP)

CEPS - Is the French pricing body for medical products

ATIH - The technical hospitalization information agency maintaining the DRG system

UNOCAM is the union of voluntary health insurers

Key regional bodies are regional agencies of health (**ARSs**), and regional unions of healthcare professionals (self-employed professionals) (**URPSs**).



Health Technology Assessment

HAS - National Authority for Health



HAUTE AUTORITÉ DE SANTÉ

- ❖ Health technology assessment
- ❖ Guidance on requests for inclusion or renewal on the positive list of reimbursed product and services Health products for therapeutic, diagnostic and handicap
- ❖ Specialist committees of HAS
- ❖ 21 experts appointed on the basis of their scientific competence
- ❖ Department for assessment of MD and diagnostic and therapeutic procedures

How CNEDIMTS works?



HAUTE AUTORITÉ DE SANTÉ

CNEDiMts

Medico-technical dossier prepared by the manufacturer:

CE marking

MD description

Clinical studies

Specific Evaluation:

Analysis of literature data

Expert

Decision of committee: **Vote**



Favorable

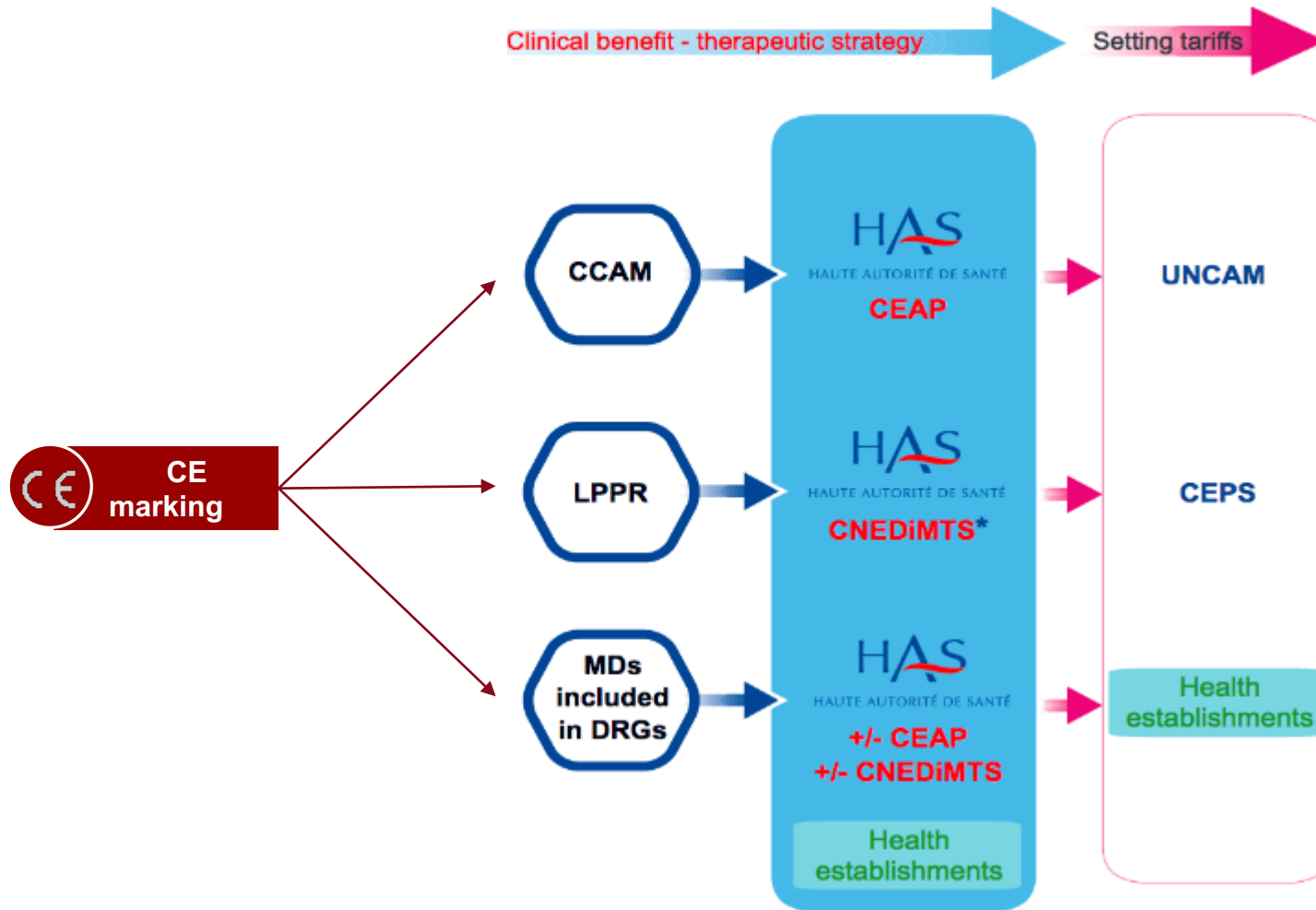


Unfavorable

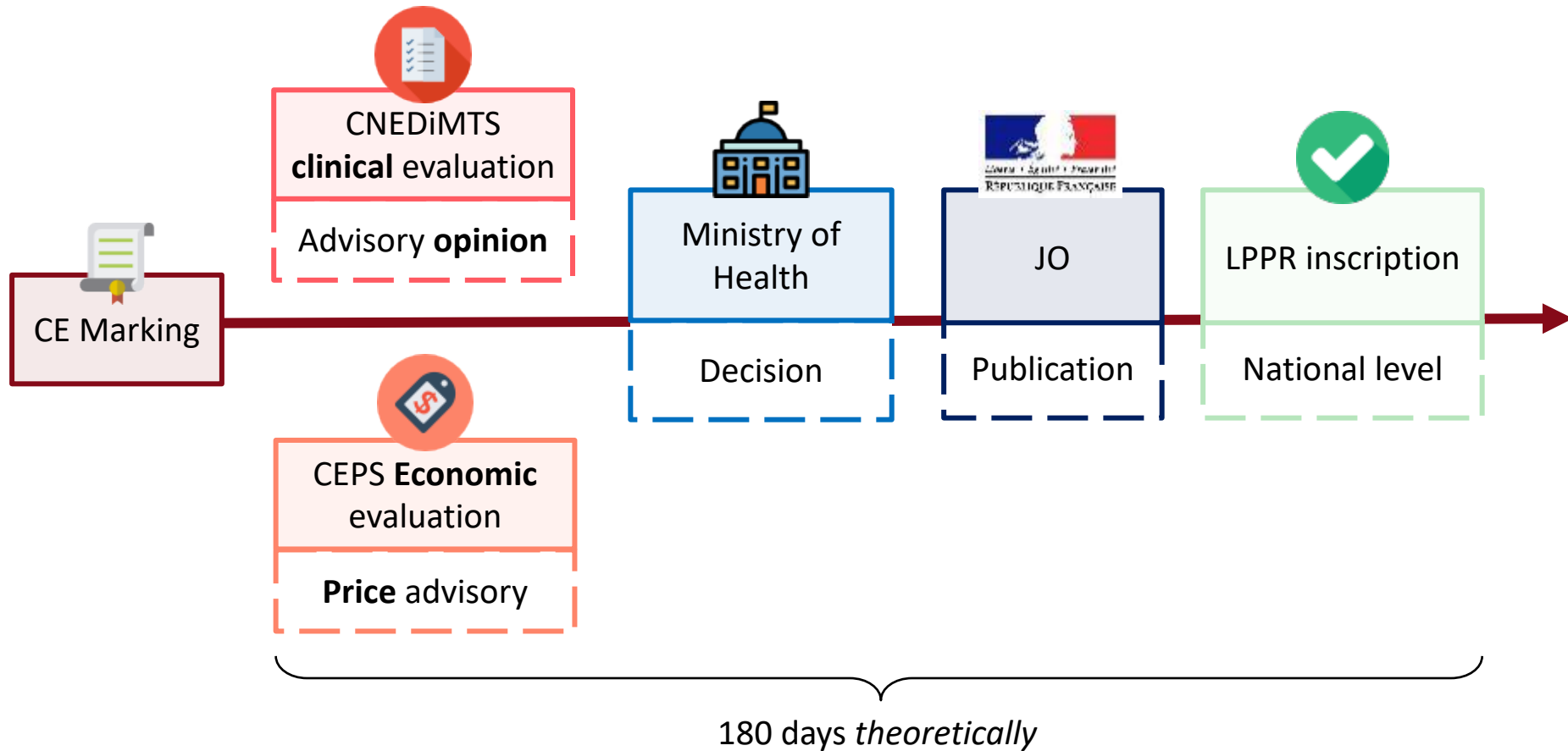
} to be included on LPPR



Medical device market access: How to process?



LPPR inscription process





Hospital Reimbursement System

4 ways to reimburse MD

CCAM

DRG/GHS

LPPR

(List of Reimbursable Products and Services)

MIGAC

CCAM

Common Classification of Medical Procedures

Common Classification of Medical Procedures (CCAM)



French medical classification for clinical procedures

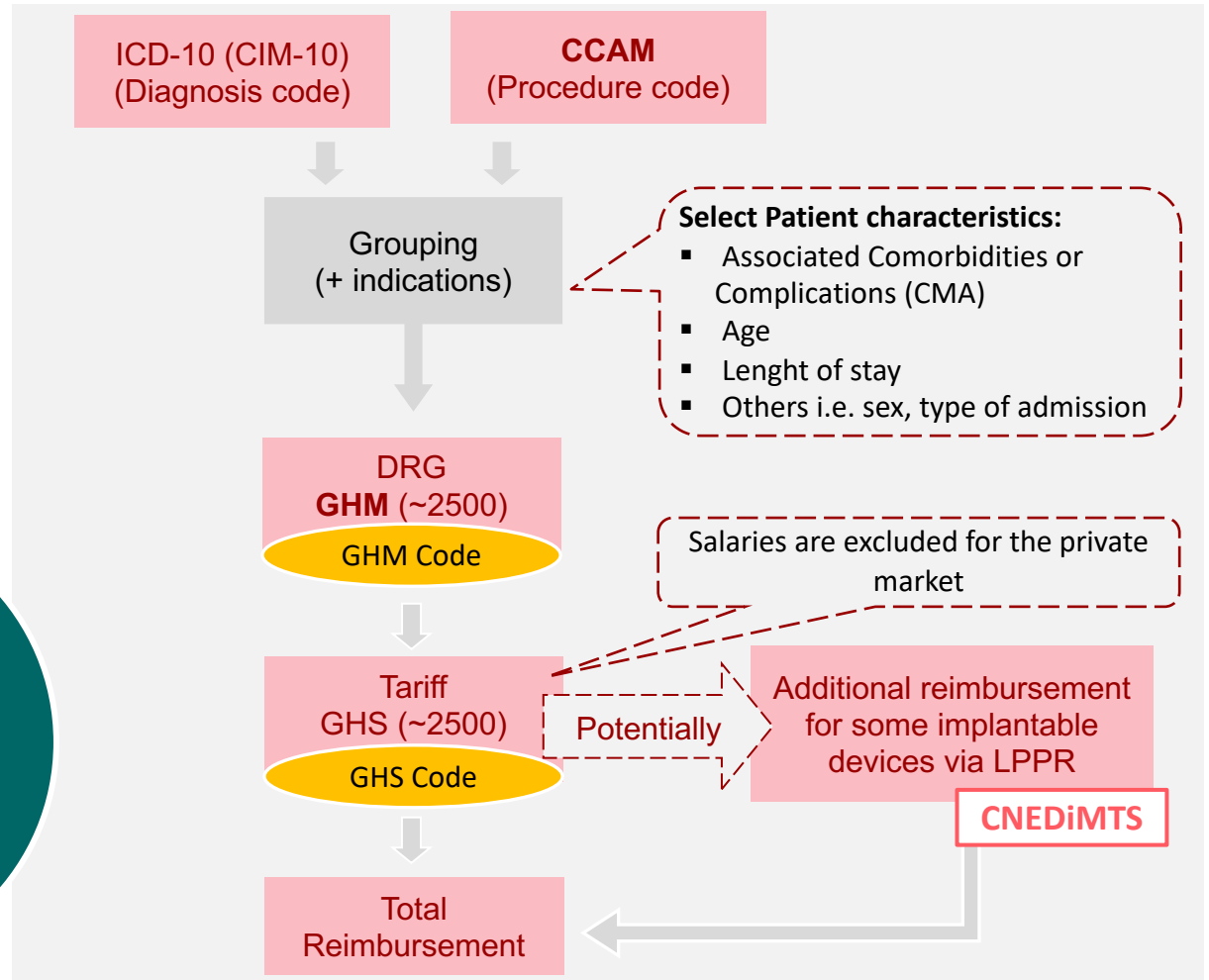
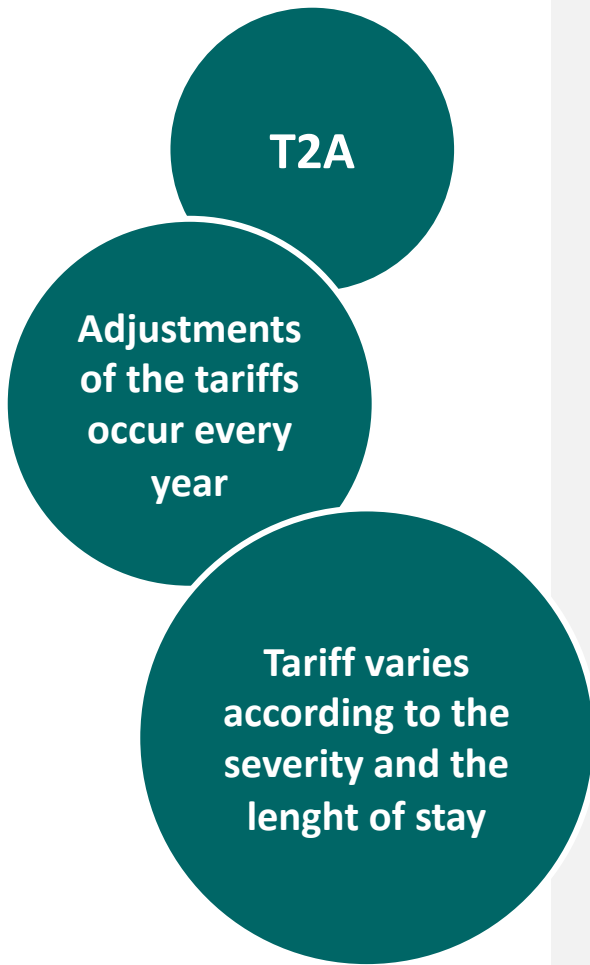
Used to establish:

- ❖ In the private ambulatory practice: fees for the acts performed during technical consultations
- ❖ In private clinics: fees for the procedures
- ❖ In public and private hospitals: contributes with the ICD codes (diagnostics) to the DRG/T2A grouping (pricing of hospital) → *Same as German OPS code*

Assessment by the CNEDiMTS

DRG/GHS (T2A)

Hospital Reimbursement System





GHS Tariff Structure: why differences between public and private hospitals?

Includes

- Medical staff
- Consumables
- Capital charges
- Drugs, medical devices*
- Wards, OR
- Diagnostic tests, Radiology
- Overhead (Logistics, laundry)

Medical staff: GHS tariffs for private for-profit hospitals do not include physician's fees and medical procedures. That explains the difference of GHS tariffs between public and private hospitals

*except those reimbursed on the LPPR



LPPR

Positive Reimbursement List of Products and Services

The French positive reimbursement list « LPPR »

List of Reimbursable Products and Services

To gain coverage through the national health insurance, MD must first be included on the national positive reimbursement list (LPPR)

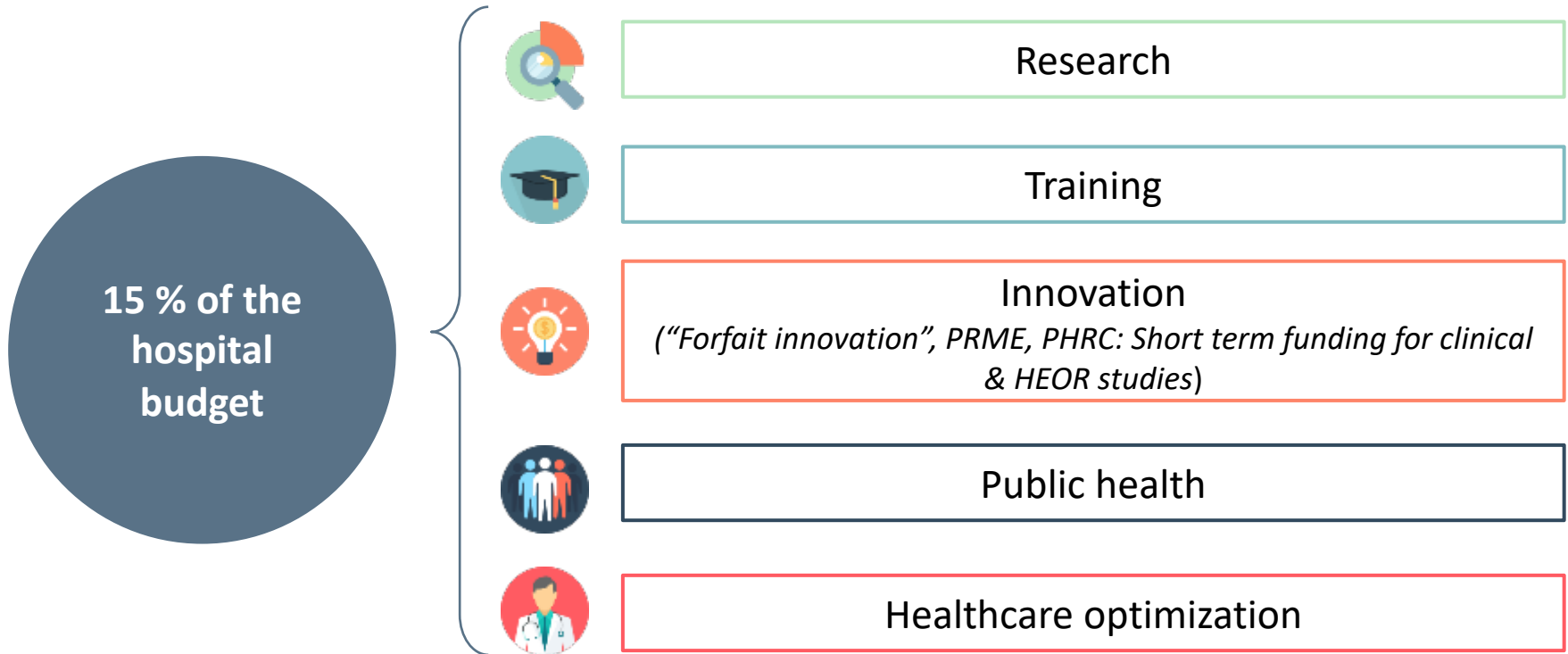
Use for:

- ❖ MD for personal use (medical aids, etc.);
- ❖ MD reimbursed in addition to the GHS tariff for both inpatient and outpatient use.

Assessment by the CNEDiMTS

The “MIGAC” funding

MIGAC: a lump sum payment



Alternative funding for innovative products

Alternative funding option for innovative products

- ✓ **Clinical hospital research programs**
- ✓ **Innovation lump sum**
- ✓ **Medico-economic research programs**
- ✓ **Article 51 of the Social Security Code**

Innovation lump sum

3 medical devices have been selected under « forfait innovation »



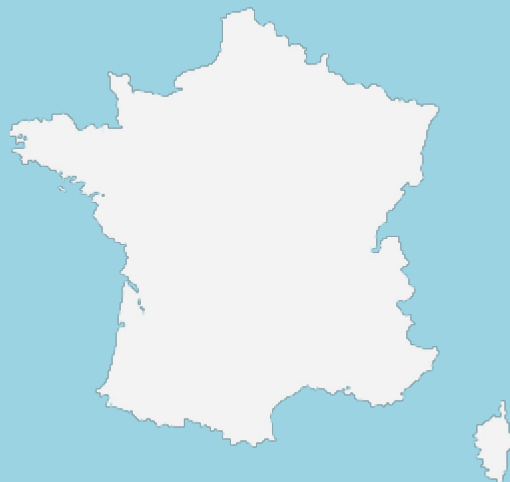
Argus II
Epiretinian Prosthesis



Ablatherm
Prostate cancer



Echopulse
Breast Cancer



TAKE HOME MESSAGES

- 1. Understand the medical need**
- 2. Know the requirements and stakeholders expectations**
- 3. Think market access from the earliest stages of development**
- 4. Avoid useless costs**
- 5. Be up to date in the moving environment!**

