

## **HEALTH BASKET PROJECT**

### **FRANCE**

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## I. OVERVIEW

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### Health insurance coverage

The financial management of health care in France is mainly undertaken by the statutory health insurance system as a branch of the wider social security system. Statutory health insurance has covered the whole population since 1 January 2000. It only funds three quarters of health spending, so there is considerable scope for complementary sources of funding.

The current structure of the health insurance system is based on its founding text, the Ordinance of 4 October 1945, and the legislative measures that have followed since then. The system has gradually been extended from covering employees in industry and commerce to covering the population in general, incorporating students (in 1948), career soldiers (in 1949), farmers (in 1961), and self-employed professionals (in 1966–1970). Statutory health insurance on a voluntary basis was introduced in 1978. Since 1 January 2000, the Universal Health Coverage Act (CMU) has completed this extension by offering basic health insurance coverage to all those legitimately resident in France. (Haut conseil pour l'avenir de l'assurance maladie, 2004, Sandier and al., 2004)

The main characteristics of the statutory health insurance system are the following :

- it is compulsory;
- it covers all households, regardless of their health status, their income, the number of people in the household, etc.;
- the field of reimbursement is somewhat uniform, with the “basket of goods and services” covered by the insurance funds being the same for all the statutory schemes, and the rate of reimbursement being almost the same. The exceptions are the local scheme in the Alsace-Moselle region, and certain specific public sector schemes.

It is estimated that more than 85% of the population have complementary health insurance. Taking into account the beneficiaries of the Complementary Universal Health Coverage (CMUC), which represents 6 % of the population, about 91% of the French population are covered by the complementary insurance scheme. (Couffinhal and Perronin, 2004)

Unlike the situation in many other countries, the French complementary health insurance scheme has a “financial” effect rather than a “thematic” coverage, in comparison with the statutory health insurance funds. In other words, the complementary insurance intervenes on the same health basket than the statutory schemes, rather on other goods and services not covered by them.

Participation in the statutory health insurance system takes place on the basis of professional status, through the health insurance funds of the different schemes. In the context of the CMU, however, participation depends on residence in France and on level of income. Any dependants of the insured person are also covered by his/her health insurance.

The three main health insurance schemes are as follows:

- The General Scheme (*Régime général* or Caisse nationale assurance maladie des travailleurs salariés: *CNAMTS*) covers employees in commerce and industry and their families (about 84% of the population), as well as people in receipt of CMU, evaluated on 31 December 2003 to number 1 500,000 people, or 2.4% of the population, (DREES, 2005).
- The Agricultural Scheme (*Mutualité sociale agricole*) covers farmers and agricultural employees and their families (about 7.2% of the population).

- The Scheme for the Non-agricultural Self-employed (CANAM) covers craftsmen and self-employed people, including self-employed professionals such as lawyers (about 5% of the population).

Other schemes cover certain categories of the population, also on a work-related basis. Several of these schemes are linked to the General Scheme, as is the case for civil servants at both local and national levels, doctors working under health insurance agreements, students, and military personnel.

Other insurance schemes, e.g. for miners, employees of the national railway company, the clergy, seamen, and the national bank, have their own particular form of organisation and function autonomously.

For historical reasons, people from the Alsace and Moselle regions, which represent 4.6% of the French population, benefit from a special scheme which offers better cover of medical goods and services in return for higher contribution rates. Here, the whole range of medical goods and services is reimbursed at 90% or 100%, in comparison with the statutory health insurance schemes where the reimbursement rates are between 35% and 100%, e.g. :

- medical biology procedures are reimbursed at a rate of 60% by the statutory schemes, and at a rate of 90% by the Alsace-Moselle special scheme;
- patient transport and emergency rescue are reimbursed at a rate of 65% by the statutory scheme, and at a rate of 100% by the Alsace-Moselle special scheme;
- minor orthopaedic appliances are reimbursed at a rate of 65% by the statutory scheme, and at a rate of 90% by the Alsace-Moselle special scheme.

The health insurance funds are under the supervision of the Social Security Directorate of the Health Ministry, which since 1996 has managed the statutory health insurance system within the framework of an agreement on objectives and management drawn up with the State every three years.

The statutory health insurance covers the whole population for a wide range of medical goods and services. The rules for reimbursement are based on several general principles:

- the health insurance system grants people access to the registered health-care professional of their choice;
- there is generally no limit to the amount of goods and services reimbursed;
- doctors have considerable freedom in prescribing, although they must comply with practice guidelines (RMOs).

In order to be eligible for reimbursement, diagnostic services, treatment, drugs, and prostheses should:

- have been provided or prescribed by a doctor, a dentist, or a midwife and distributed by health-care professionals or institutions registered by the statutory health insurance system;
- be listed on the positive lists currently in operation, i.e. the official schedules of procedures for different health-care professionals and the list of reimbursable drugs or materials.

The amount reimbursed by the statutory health insurance system is calculated for individual goods or services by applying a coverage rate (expressed as a percentage) to the negotiated charge. Patients are generally expected to pay the health-care provider themselves and then claim total or partial reimbursement of their expenses from their complementary health insurance fund. This rule does not apply in the case of hospitalisation as the hospital is paid directly by the health insurance funds, nor does it apply to any type of care received by those in receipt of CMU. Direct payment of providers by the health insurance funds is becoming increasingly common in ambulatory care, particularly in the pharmacist and laboratory sectors.

## Principles of reimbursement

The French health insurance system offers wide-ranging reimbursement within the fields of preventive, curative, rehabilitative, and palliative care. The legal definition of the whole range of goods and services reimbursed by the statutory scheme is laid down in article L.321-1 of the Social Security Code (SSC).

The medical goods and services, which are qualified for reimbursement by the health insurance system, include (Sandier et al., 2004):

- the cost of hospital care and treatment in public or private institutions providing health care, rehabilitation, or physiotherapy;
- the cost of outpatient care provided by general practitioners, specialists, dentists, and midwives;
- diagnostic services and care prescribed by doctors and carried out by laboratories and paramedical professionals such as nurses, physiotherapists, and speech therapists, etc.;
- the cost of pharmaceutical products, medical appliances and prostheses prescribed and included in the positive lists of products eligible for reimbursement;
- the costs of prescribed health care-related transport.

The general conditions of the reimbursement system are established by law. According to article L.322-2 of the SSC, the insured person's co-payment is fixed by a decree in the Council of State. The co-payment can be either a percentage of the charges, or a lump sum. It can vary according to the type of services and the conditions in which they are provided, the type of accommodation and establishment, and the treatment given. The co-payment can also depend on the age of the insured person, e.g. the reduced rates paid by beneficiaries of the National Solidarity Fund, or their family status. On the other hand, however, the French health insurance reimbursement system does not take into account the insured person's income.

The health benefit basket is explicitly defined by positive lists of goods and services. These lists generally contain a rate for each item, which is used to calculate the reimbursement by health insurance funds.

These lists only apply to goods and services delivered by private sector professionals, in their own practices, or in private for-profit hospitals.

The coverage of public sector hospital services is defined in greater detail since public hospitals are paid for by global budget. This implies that every service dispensed is *de facto* reimbursed.

Acceptance for reimbursement is actually only legal when the goods or services are provided in an appropriate medical context. The reimbursement of all goods as well as all paramedical procedures is dependant on the provision of a prescription, which serves as proof that such goods and services were actually necessary. For some types of treatment, such as physiotherapy and spa treatment, prescription by a physician is not a sufficient condition for reimbursement. Coverage by statutory health insurance is subject to the prior authorisation (*entente préalable*) of the doctors advising the health insurance funds, after examination of the patient's case history and the possible interviewing of the patient.

Article L.162-17 of the SSC states that the list of reimbursable medical conditions "specifies the only indications that give entitlement to the reimbursement of drugs." Other regulations other than the lists and nomenclatures can also specify the conditions for reimbursement, as is the case with the Medical Practice Guidelines (RMO), e.g. :

**Box 1**  
**An example of mandatory practice guideline**

There is no cause to request or to perform a scan and/or magnetic resonance imaging for the diagnosis or monitoring of spinal arthritis, apart from those cases where clinical and/or para-clinical data and standard X-rays give rise to the fear of a complication or of another kind of spinal disease.

There is no cause to request or to perform a scan and/or magnetic resonance imaging in the case of acute lumbago or stress lumbago, apart from those cases where the clinical and/or para-clinical data give rise to the fear of symptomatic lumbago (lumbago indicative of an infectious, inflammatory, tumorous, or extra-spinal disease).

In the case of common types of lumbago:

- So-called direct analgesic physiotherapy techniques, especially massage and locally-applied heat treatment, are most frequently perceived as sedative by the patient. However, there is no proof of their long-term effectiveness in the treatment of chronic lumbago.
- So-called direct analgesic effect techniques are only adjuvant and must not therefore form the principle part of the physiotherapy session.
- Physiotherapy treatment can only be prescribed after a medical assessment with precise treatment objectives which will be taken into account in the assessment of the results.

There is no cause in the case of acute lumbago (acute lumbago is defined by pain which has been developing for less than 3 months whose intensity is such that daily personal or professional activity cannot be maintained at the same level) to prescribe physical rehabilitation sessions.

There is no cause to prescribe, at the first consultation, more than 15 physiotherapy sessions for chronic lumbago.

Source : National Agreement between sickness funds and physicians, 1999, Annexe I, theme 58.

Until 2004, positive lists were officially enforced by ministerial orders which gave details of the inclusion of new goods and services. Ministers used to make their decisions on the advice of *ad hoc* scientific commissions such as the Transparency Commission (described in part III) or agencies, especially the National Agency for Accreditation and Evaluation in Health Care (*Agence Nationale de l'Accréditation et l'Evaluation en Santé*, ANAES). The inclusion of all procedures (medical procedures and medical biology procedures) on the positive lists depended upon the ANAES' advice.

The National union of health insurance funds (*Union Nationale des Caisses d'Assurance Maladie*, UNCAM), which includes representatives of the three main sickness funds, has defined the positive lists of procedures, drugs and devices since the Act on Health Unsurance of 13 August 2004. The sickness funds will be assisted in their decision-making by the advice of the two newly-created bodies: the High Health Authority (*Haute Autorité de Santé*) which replaced the ANAES and the Union of Voluntary Health Insurers (*Union Nationale des Organismes d'Assurance Maladie Complémentaire*, UNOC).

The Ministers of health and social security retain the right to refuse UNCAM's decisions and to include or exclude goods in or from the list, especially where public health issues are concerned. There is a time limit of one month for the rejection of decisions taken by UNCAM. This is an important change as before the 2004 Act, ministers could take several months to decide whether or not a procedure should be included on the positive list, and the procedure could not be reimbursed during this period. Moreover, they were not obliged to justify their decision.

UNCAM (and not the State) is also responsible for setting the tariffs for medical procedures, drugs and devices (instead of the State), and for determining the levels of copayment and coinsurance.

According to articles L.162-1-7, L.162-17, and L. 165-1 of the SSC, the reimbursement of medical goods and services by the statutory health insurance funds in France depends on their registration in positive lists. In April 2005, the six lists are:

- the *Nomenclature Générale des Actes Professionnels* (NGAP) ;
- the *Nomenclature des Actes de Biologie Médicale* (NABM) – for health care services;
- the *Liste des Spécialités pharmaceutiques Remboursables* (LSPR) and the *Liste des spécialités agréées aux collectivités* (LSAC) for pharmaceuticals ;
- the *Liste de Produits et Prestations Remboursables* (LPP) – for medical devices and related services;
- the *Classification commune des Actes Médicaux* (CCAM) – for medical procedures.

The implementation of the CCAM, replacing the NGAP, will change the situation within the next few months. Nowadays, this classification is only available for physicians' technical procedures(see below).

According to the article L.162-1-7 of the SSC, in some cases, innovative procedures can be included on the positive list, while the clinical research is being performed.

The range of services covered by statutory health insurance does not include cosmetic surgery, and some other treatments and services of uncertain effectiveness (e.g. spa treatments). The issue of the allocation of scarce resources means that choices have to be made, and this may result in the non-reimbursement of certain procedures, e.g. the measurement of bone density when performed in the private sector as a preventive measure, or the imposition of limits on the frequency for which they can be reimbursed, e.g. mammography for cancer screening purposes.

Within the Complementary and Alternative Medicine (CAM), special recognition has been accorded to acupuncture and homeopathy. These two therapies are thus recognised and may be legally practised, but only by medical doctors. Conversely, osteopathy and chiropractic are not included in the positive list, but doctors practising these therapies can assimilate them to other procedures included in the NGAP. Nevertheless, a few chiropractic procedure were recently included within the new CCAM classification.

When a sick person has symptoms of an unusual disease which justify medical procedures not listed in the 'nomenclature' list, these procedures can, exceptionally, be put into the same category as a similar procedure included in the 'nomenclature' list, and can therefore be allocated the same key-letters and coefficients (see below). The reimbursement of such procedures is dependant on the approval of a medical advisory committee and the carrying out of prior authorisation formalities (article 7 of the NGAP).

All the various types of goods and services reimbursed by statutory health insurance have their own particular negotiated rate. This rate serves as the basis for calculating the total amount reimbursed to the patient, even if the prices actually charged in practice are higher than the official standard rate in question (extra-billing). The extra-billing basically concerns the payment of certain health professionals, dental repair work, and spectacles and other optical appliances, and accounted for an expenditure of about 8.6 billion euros in 2003 (Haut Conseil de l'assurance maladie, unpublished data). This extra-billing represents 14.2% of specialist total fees, 5.6% of those of GPs and 47.9% of those of dentists (Point Stat n°40, 2003).

A general principle of financial coverage by statutory health insurance is for the health insurance fund to retain a proportion of the total cost of treatment (partial reimbursement). This proportion must therefore be paid by the patient and is equivalent to statutory co-payment. The patient's contribution to the total cost of treatment varies according to the type of treatment, and is higher for outpatient care and drugs than for hospital treatment.

In certain circumstances, patients are exempt from these co-payments and their health insurance fund then covers the total cost of treatment. According to the in article L.322-3 of the SSC, the conditions of exemption from co-payment are fixed by a decree in Council of state. The cases of exemption are:

- Those Exemptions linked to health status, in particular when the insured person is suffering from one of thirty specified long-term illnesses so called '*Affection de longue durée*' (ALD), such as diabetes, AIDS, cancer, or psychiatric illness, or if the patient is suffering from one or several incapacitating diseases.
- Recipients of disability pensions, widow's pensions, or military pensions. (The exemption does not concern '*vignette bleue*' (blue label) drugs, which are reimbursed at a rate of 35%);
- Recipients of a benefit related to work injury whose incapacity is rated higher than 66.66%. (The exemption does not concern '*vignette bleue*' drugs, which are reimbursed at a rate of 35%);
- Pregnant women during the final four months of pregnancy. (The exemption does not concern '*vignette bleue*' drugs, which are reimbursed at a rate of 35%);
- Newborn babies hospitalised within thirty days after birth. (The exemption does not concern '*vignette bleue*' drugs, which are reimbursed at a rate of 35%);
- Hospitalisation due to child abuse;
- Disabled people under the age of 20;
- Medical procedures with coefficients higher than 50;
- A period of hospitalisation of more than thirty days. (The exemption does not concern '*vignette bleue*' drugs, which are reimbursed at a rate of 35%);
- Diagnosis and sterility treatment.

The Long-Term Illness (ALD) scheme concerns over 12% of insured people and represents 48% of health expenditure. The other status-based exemption categories are negligible. The direct cost of exemptions is estimated at 18 billion Euro, or 18% of the reimbursed expenditure (Haut conseil pour l'avenir de l'assurance maladie, p. 36-37).

Exemptions on economic grounds do not exist, but the CMU provides complementary voluntary health insurance coverage for people on low incomes, and this has the same effect as an exemption on economic grounds.

Any difference between the amount actually paid by the patient and the amount reimbursed by the health insurance fund (the patient's co-payment plus any amount in excess of the official charge) has to be paid by the insured person or, where applicable, by their complementary voluntary health insurance fund.

## **II. DEFINITION OF ENTITLEMENTS AND BENEFIT CATALOGUES BY LEVEL**

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In France, health benefit catalogues are drawn up at national level. Lists of reimbursable products and services are the same for all those insured, irrespective of their statutory health insurance scheme. Since 2000, the three main insurance schemes offer the same reimbursement rates.

The inclusion of goods and services on the lists means that they are subject to the setting of a rate or fee.

### **Curative care service (HC.1)**

#### **II.1.1. In-patient curative service (HC1.1)**

The situation about the coverage of hospital services is difficult to describe because the Social Security Act of 2004 has changed the rules and its implementation is in progress.

Before 2004, the rules were not the same for all types of hospitals and were dependant upon each hospital's status. The range of medical procedures and the basket of reimbursable drugs were defined (at least for the private sector), but it was not the case for other services, such as nursing care. In addition, positive lists were often implicitly defined through the hospital payment systems.

However, this situation should be changing during the next few years for at least two reasons. Firstly, the positive list for physicians' procedures is common to both private and public hospitals (article 162-1-7 of the SSC), and, secondly the implementation of the per-case payment reform means that both sectors will be brought into line. Furthermore, the definition of reimbursable drugs is clear and common to the two sectors.

Paramedical services such as occupational therapy linked with medical procedures for inpatient treatment are reimbursed due to the only fact that they are provided within the medical services.

#### **(a) Services covered in public and private-not-for profit hospitals, mainly financed by global budget**

Before 2004, there was no positive list to define reimbursable services, but rather an implicit coverage of all services provided in public and not-for profit hospitals. However, the people we interviewed at the Ministry of health agreed that not all services, e.g., cosmetic surgery, are reimbursable

The implementation of the per-case payment system is about to change and simplify the entire situation as all medical, surgical and obstetrical (MSO) services in all hospitals will apply this system, independently of their status. The reform establishes several means of financing medical activities:

- Services provided in in-patient or out-patient acute care will be financed through a payment-per-case system. This is based on a DRG-type classification of homogeneous stays (GHS for *Groupes homogènes de séjours*);
- Outpatient procedures will be paid on a fee-for-service basis;
- Organ retrieval and emergency services will be paid on a fee-for-service basis, mixed with annual lump-sum payments;
- High costly drugs or medical devices will be paid separately.

This payment system also includes earmarked 'MIGAC' (for *Missions d'intérêt général et Aide à la contractualisation*) funding to finance other activities. These funds can not only finance hospitals' participation in general interest operations in the fields, for example of research, education but can also finance some medical care activities promoted by contracts between hospitals and regional health agencies, such as the setting up of network, mobile teams of geriatrics or palliative care, *telemedecine*.

#### **(b) Services covered in private-for profit hospitals**

Until 2004, private-for-profit hospitals were paid on a per diem basis for in-patient stays, regarding such items as nursing care, current pharmaceuticals and accommodation. However, the new GHS payment system has been in operation since 1 March 2005.

Procedures carried out by doctors are always paid separately and directly to doctors concerned, on a fee-for-service basis. In March 2005, the fee-schedule, which is used, is the General Nomenclature of Professional Procedures (NGAP, see § II.1). This nomenclature can be considered as the positive list for private for-profit hospitals, as health insurance funds would not finance any stay if one of these procedures did not apply. It is, however, about to be replaced by a new catalogue of procedures called the Common Classification of Medical Procedures (CCAM, presented in § III).

There is therefore a positive list for physicians' procedures e.g. medical imaging and radiotherapy, while all other types of care provided by private-for-profit hospitals are financed through per-case-payment.

### **(c) The status of drugs and medical devices delivered in hospitals**

Drugs provided in hospitals must be included in the list of hospital drugs (LSAC for *Liste des spécialités agréées aux collectivités*), described in Part III.4.

Similarly, medical devices must be included in the list of reimbursable 'medical devices' and their related services (*Liste des Produits et Prestations - LPP*), described in part III.5.

### **(d) Entitlements and level of reimbursement**

All the services provided before or after a period of hospitalisation during which medical treatment is carried out are reimbursed by the health insurance fund at a rate of 70% or 60% according to the type of service provided.

Patients have to pay a per diem hospital lump sum, which represents the patient's financial participation in the accommodation charges during his hospitalisation. The per diem hospital lump sum has been 14 euros since 1 January 2005, except in the case of psychiatric services, where the per diem hospital lump sum is 10 euros.

The hospital lump sum is reimbursed at a rate of 100% in several cases :

- Hospitalisation due to childbirth, during the last 4 months of pregnancy, and during the 12 days after labour;
- Hospitalisation of a newborn child within thirty days of its birth;
- Disabilities affecting a person under the age of 20;
- War invalids with a disability rate of higher than 85%;
- Victims of accidents at work and occupational diseases;
- Those covered by the local health insurance system in Alsace and Moselle;
- Those entitled to Universal Health Coverage (CMU) or of the State Medical Aid (AME).

### **Hospitalisation in a public hospital or a private non-profit hospital**

Hospital charges are reimbursed at a rate of 80% by the health insurance fund. The patient is responsible only for his/her part of the co-payment, i.e. 20% of the hospital fees and the excess charges.

During a period of hospitalisation some expenses, such as those for the provision of extra comfort, e.g. a single room, and any excess consultation fees are not reimbursed by the health insurance fund.

In general, patients are charged for the per diem hospital lump sum and for the '*ticket modérateur*' (their co-insurance), but they only actually pay for whichever one is the most expensive.

### **Hospitalisation in private for-profit clinics**

In private clinics, the patient has to pay for all the services provided, after which the insurance fund can reimburse part of the charges.

Hospital charges are reimbursed at a rate of 100% by the health insurance fund when :

- The coefficient of the medical procedure is higher than 50;
- The period of hospitalisation lasts for more than 30 days;

- Hospitalisation due to labour, the last 4 months of pregnancy, or the 12 days after labour;
- Hospitalisation of a newborn baby within 30 days of labour;
- Hospitalisation due to accidents at work and occupational diseases;
- Hospitalisation due to a long-term disease;
- Hospitalisation due to child abuse;
- Recipients of an allowance paid due to an accident at work with a resulting incapacity rate higher than 66.66%;
- Recipients of disability pensions, widow's pensions, or military pensions;
- Those covered by the local health insurance system in Alsace and Moselle;
- Those entitled to Universal Health Coverage (CMU) or to State Medical Aid (AME).

The total reimbursement of hospital charges does not concern the per diem hospital lump sum, which must still be paid.

#### Medical services provided before or after a period of hospitalisation

All the services provided before or after a period of hospitalisation during which medical treatment is carried out are reimbursed by the health insurance fund at a rate of 70% or 60% according to the type of service delivered, e.g. for an operation on the knee :

- the pre-operative anaesthetist's consultation is reimbursed at a rate of 70%,
- post-operative medical care is reimbursed at a rate of 60%.

Doctor's fees for outpatient consultations in hospitals are reimbursed at a rate of 70%, and the fees of medical auxiliaries' services provided in their own practices are reimbursed at a rate of 60%.

#### **II.1.2. Day-out patient curative care**

The rules are the same as those applicable to in-patient care as far as the definition of the health basket is concerned.

#### **II.1.3. Out-patient curative care**

The general fee schedule (*Nomenclature Générale des Actes Professionnels* - NGAP) specifies the list of medical procedures which are reimbursable when delivered by licensed health professionals in private practice, whether in their own consulting rooms or in private for-profit-hospitals.

Until the reform of 13 August 2004, the NGAP was updated by ministerial order, on the advice of a Commission, composed of representatives both health insurance funds and professionals bodies. The National Union of health Insurance Funds is updating the positive list in the near future,.

The '**Nomenclature Générale des Actes Professionnels**' (NGAP) was created by a ministerial decree of the Ministries of Health and Social Security on 29 October 1945. Since then, although the NGAP has been the subject of regular revision, it still retains many of its original features. One of the most important changes, introduced in 1972, was the new classification of medical procedures based on anatomical parts and not on specialities. From 1991 to 1994, the proposals for modification of the nomenclature were always related to the introduction of 'economic approaches' (cost assessment) to reflect its changing role from a simple classification tool to an instrument for the management and cost containment of the health system (Zizine Hbert, 1995, p. 46).

The NGAP catalogue describes medical activities, which are reimbursable by the statutory health insurance funds and also specifies rates for medical procedures, when they are performed in the

private sector in France. For each service, the NGAP allocates an item, a coefficient and a key letter (varying according to the speciality of the professional involved) which give the rate of the service when multiplied by the current value of the key letter. This determines the professional fees of general practitioners, specialists, dentists, midwives, laboratory directors, physiotherapists, speech therapists, orthoptists, and chiropodists working in private practice.

This Nomenclature is used in public hospitals to assess outpatient care and to specify the rate of reimbursement. In private-for-profit hospitals, the NGAP is also used to determine the charges for operating rooms.

As seen before, auxiliary services provided by nurses, physiotherapists and orthoptists, etc must be provided on medical prescription in order to be reimbursed.

After the coming into effect of the CCAM, the NGAP will only deal with issues, which are not yet covered by the CCAM, i.e. medical, clinical, and technical procedures provided by other health professionals.

#### ***II.1.4. Services of curative home care***

Reimbursed services in curative home care are of three types:

- Services delivered by independent doctors (home visits);
- Services of other professionals, such as nurses;
- Hospital-at-home services.

#### **Reimbursement of palliative care at home**

According to article R 162-1-10 of the Social Security Code, a multidisciplinary team of health professionals can be organised, at the special request of a person whose state of health demands it, to provide palliative home care. The remuneration can be paid on a fee for service basis or as a lump sum.

The insurance fund is participating, on an experimental basis, in the support of home palliative care for those insured under the General Scheme by allocating them treatment not normally covered by other legal provision. Such treatment is means-tested and includes:

- the reimbursement of expenses incurred in caring for the sick person at home,
- the reimbursement of drugs which are legally not reimbursable.

Prospective beneficiaries of this palliative care have to satisfy several requirements :

- Patients at a progressive or terminal phase of their illness, attended by:
  - the Home Hospitalisation Service (HAD),
  - a mobile palliative care team,
  - a specialist palliative care network,
  - in the absence of any of the above, the Home Nursing Care Service (SSIAD).
- The upper income limit is:
  - 1<sup>st</sup> level: 20,000 Euro annual income for a single person and 33,000 Euro for a couple,
  - 2<sup>nd</sup> level: annual income between 20,001 and 30,000 Euro for a single person and between 33,001 and 40,000 euros for a couple.
  - The upper income limit is increased by 3,600 Euro a year per dependent child.

The maximum amount of reimbursement is: 2,655 Euro for the first level, and 2,265 Euro for the second level, per episode of care.

These extra legal benefits allow the reimbursement of some medical supplies and drugs which are generally not reimbursable. The co-payment chargeable to the patient is at a rate of 10% for the first level and 15% for the second level.

## **Services of rehabilitative care (HC.2)**

### ***II.1.5. Services of rehabilitative health care at home***

Services of physiotherapists, speech therapists or orthopists can be delivered at home if the physician prescribe it for medical reasons.

Occupational therapy and dietetic treatment are not reimbursed when provided at home, while they are reimbursed in hospitals.

## **Services of long-term nursing care**

Long term care includes institutional and home-based care. Institutional care is provided in long-stay hospitals, clinics and nursing homes. Home base care includes nursing care and social services (home help, meals). The distinction between nursing and social care is important due to different type of coverage and financing. Health insurance covers the nursing component of care in the long-stay sections of hospitals or private clinics and retirement homes with a medical section. Users pay for the accommodation costs in hospitals and residential homes, except those who benefit from social allowances. At home, nursing services are reimbursed by national health insurance, if medically prescribed. Furthermore, since 2002, the frail elderly over sixties may be eligible to receive an allowance to pay for services other than nursing care in order to retain their autonomy as long as possible. This allowance is paid for the greater part by the local authorities and from the 'national autonomy public fund'. The assessment of a person's eligibility is need-based and performed by a local team of nurses and social workers under the supervision of a physician.

## **Ancillary health services**

### ***II.1.6. Medical analysis laboratory***

The **Nomenclature des Actes de Biologie Médicale** – NABM was created by the law of 3 April 1985. It has the same functioning and the same role as the NGAP but only concerns laboratory tests.

The new catalogue '*Classification commune des actes médicaux*' (CCAM) will replace the existing NGAP and NABM. Its implementation has been postponed several times and is now in operation for specialists' activities, since the end of March 2005. The CCAM is also being used within the field of the 'Programme for the Medicalisation of Information Systems' (PMSI).

The CCAM presents a list of coded procedures, which are common to both the private and public sectors. It contains a detailed description of each medical procedure, and it is expected to provide both fairer standard tariffs per procedure within the private sector and better hospital resource allocation within the framework of the new prospective payment per case (Polton, 2003)

This new mode of payment has been applied to all activities in medicine, surgery and obstetric services of private-for-profit hospitals, since 1 March 2005 and to about 25% of these activities in the

public sector. It is based on a DRG-type classification (*Groupes homogènes de séjours - GHS*) which uses CCAM as the basic classification for medical procedures. List of reimbursable goods

#### **II.1.7. Diagnostic imaging**

Imaging diagnostics are included in the General fee schedule for health professionals.

#### **II.1.8. Patient transport**

Transport charges are only reimbursed when:

- Transport is related to a hospitalisation;
- Transport is related to treatment of a long-term illness;
- Transport is related to an accident at work or to an occupational illness;
- Transport is by ambulance;
- A series of transport related to one treatment – at least 4 trips of more than 50 km over a period of 2 months;
- Long-distance transport – more than 150 km;
- Transport related to a formal request for medical examination (from the insurance fund medical service, the regional disablement commission, for a medical consultation concerning orthotics and prosthetics, or for a visit to a supplier of orthotic and prosthetic appliances).

In all other cases, the transport charges are not reimbursed even when prescribed by a specialist. Transport expenses of people accompanying the patient are only reimbursed for public transport.

#### **II.1.9. All other miscellaneous ancillary services**

Spa treatment is reimbursed by the insurance fund when it is prescribed by a specialist and if:

- the proposed treatment is on the list of reimbursable treatments;
- the spa centre is accredited by the insurance fund;
- the time and the number of sessions respected.

The reimbursable treatments are treatments of: orolingual mucous membrane infections, digestive infections, psychosomatic infections, urinary infections, dermatology, gynaecology, cardioarterial diseases, neurology, phlebology, rheumatology, child development problems, and respiratory tract infections.

Medical fees for spa treatment include:

- A medical observation charge which is reimbursed at a rate of 70 % on the basis of an agreed fixed charge of 64.03 Euro;
- Complementary medical treatment is reimbursed at a rate of 70%.

The fixed spa charge is reimbursed at a rate of 65% on the basis of agreed charges.

Transport and accommodation charges are reimbursed only if the annual income of the patient's household is lower than the upper income limit.

- Transport charges are reimbursed at a rate of 65%.

- Accommodation expenses are reimbursed at a rate of 65% on the basis of a fixed accommodation charge of 150.01 Euro.

The amount of the upper income limit in 2004 was 14,664.38 Euro, plus an increase of 50% for the spouse and for every other person so entitled.

Special reimbursement measures are implemented for spa treatment linked with a period of hospitalisation. The hospitalisation expenses are reimbursed at a rate of 80%.

## **Medical goods dispensed to out-patients (HC.5)**

### ***II.1.10. Pharmaceuticals and other non-durables (HC.5.1)***

#### **Prescribed pharmaceuticals (HC.5.1.1)**

To be reimbursed, pharmaceutical must be:

- included on the list of reimbursable pharmaceuticals (Liste des Spécialités Pharmaceutiques Remboursables aux Assurés Sociaux - LSPRAS) ;
- be prescribed by a physician, a dentist or a midwife.

The procedure for the registration of drugs for reimbursement has three stages:

- Market authorisation (Autorisation de Mise sur le Marché - AMM) is given either within the framework of a European procedure by the European Agency for Drugs, or within the framework of a national procedure by the 'Agence Française de Sécurité Sanitaire des Produits de Santé' (AFSSAPS), after advice from the AMM Commission. This Commission checks the drugs' effectiveness, safety, and quality. (Haut Conseil pour l'Avenir de l'Assurance Maladie, 2004).
- Reimbursement registration – After the consent of the AMM has been obtained, reimbursement is dependant upon inclusion on the 'positive' list of reimbursable proprietary medicines (Liste des Spécialités Pharmaceutiques Remboursables - LPSR). The request for inclusion is made by the pharmaceutical manufacturer. The inclusion on the list and the determination of the rate of reimbursement are established by a health and social security ministerial order after advice has been obtained from the Commission de la Transparence (Transparency Commission).
- Price negotiation –The Transparency Commission's advice is forwarded to the Economic Committee for Medical Products (CEPS), which negotiates the price of drugs with the manufacturer. The product can then be included on the list.

The request for reimbursement is made by the pharmaceutical manufacturer (article R.163-8 of the SSC). However, since it is not necessary for a drug to be reimbursable to be prescribed, a pharmaceutical company can decide not to file a request for reimbursement in order to be able to keep its own freedom of pricing.

The positive list of reimbursable drugs is established by orders of the Ministries of Health and Social Security on the advice of the Transparency Commission and the Economic Committee for Medical Products (CEPS).

Inclusion on the positive list of reimbursable drugs depends on two factors (article R.163-1 – 163-14 of the SSC). The drug has to contribute either:

- to an improvement in the prescribed treatment, evaluated in relation to other drugs in the same therapeutic class, or
- to a decrease in the cost of treatment.

- Since October 1999, evidence of a drug therapeutic value (*service médical rendu* - SMR) must be supplied in order for it to be included on the positive list (see part III for details).

The price of drugs purchased in community pharmacies, is then set by negotiation between the Economic Committee for Medical Products (CEPS) and the manufacturer.

The drug's price is set with regard to the improvement it provides in comparison with other drugs on the positive list in the same therapeutic class, the price of other drugs with same therapeutic indications and the estimated volume of sales, and both the expected and current conditions of its use.

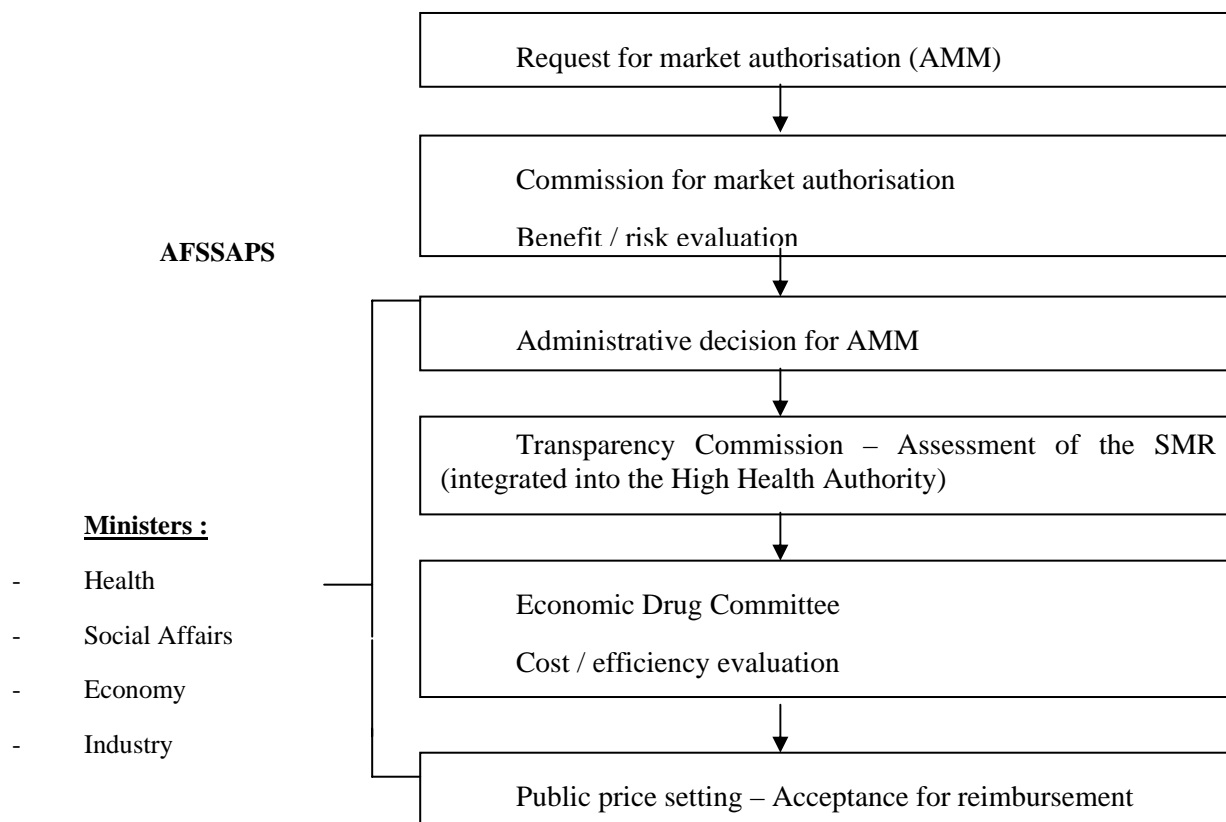
The administrative and financial circuit of drugs in hospital is subject of special regulation:

- there is a specific list of drugs approved for hospital use, defined by the ministers of health and social security, following the advice of the Transparency Commission;
- some drugs can be sold without market authorisation, but with temporary use authorisation (autorisation temporaire d'utilisation - ATU);
- the prices of approved drugs are freely negotiated between hospitals and pharmaceutical laboratories (except for listed costly innovative drugs since 2004)
- The health insurance reimbursement rate for retroceded drugs is 100%.

More than a half of the 8,250 drug presentations (corresponding to 4,570 different drugs) available on the French market are included in the positive list of reimbursable drugs, which lists 4,500 products. Reimbursable drugs account for 91.5% of the turnover of pharmacies (Sandier and al. 2004).

Some homeopathic medical products are reimbursed.

**Diagram 1: Drugs administrative circuit**



There are different rates of reimbursement for drugs:

- Drugs considered to be ‘not substitutable and particularly expensive’ are fully reimbursed – 100%;
- Drugs ‘mainly used for the treatment of disorders not usually of a serious nature’ are reimbursed at a rate of 35% (‘vignettes bleues’ – blue label), and
- other drugs (for the most common illnesses) are reimbursed at a rate of 65% (‘vignettes blanches’ – white label).
- Magistral preparations and pharmacopoeia products are reimbursed at a rate of 65%.

Since September 2003, more than 450 drugs have been reimbursed on a set price basis: the set reference price is calculated on the basis of the price of generic drugs. The patient is responsible for paying the co-payment.

### **OTC drugs (HC.5.1.2)**

Some drugs are both available without prescription and included on the positive list. However, they need a medical prescription to be reimbursed.

In no circumstances are drugs purchased without prescription reimbursable.

### **Other medical non durable (HC.5.1.3)**

To be reimbursable non-durable medical goods must be included in the positive list for medical devices (see below) and prescribed by a doctor.

### ***II.1.11. Therapeutic appliances and other prosthesis (HC.5.2)***

According to article L.165-1 of the SSC, the reimbursement of medical appliances, human cellular tissue, health products other than drugs, and related services is dependant upon their inclusion on a list drawn up after advice from a the Commission on medical devices and related services.

This list positive list for devices and their related services (LPP for '*Liste des produits et prestations*') is established by ministerial order. Reference prices are set for each product, which will be the basis for health insurance funds reimbursement. Rates of reimbursement vary from 65% to 100%, according to the type of good.

The reimbursement system concerning 'medical devices' generally leads to discrepancies between the reimbursement tariff and real market prices. When it is judged necessary, in order to provide equality of access or of compensating a disability, the only way to get rid of such a discrepancy, the only way of doing this is to set the sale price. Nevertheless, whether or not set sale prices are used, the differences between the reimbursement tariff and the actual prices are considerable (CEPS, 2004), especially for :

- orthoses (30 to 40% of the user charges);
- hearing aids for adults (75 to 88% of the user charges);
- spectacles and contact lenses, for which General Scheme reimbursements in 2003 were 142 million Euro, representing only 7 to 8 % of the corresponding sales total).

#### **Glasses and other optical products (HC.5.2.1)**

Glasses and medical products are reimbursed up to 65% of reference prices.

In France, reference prices ('*tarifs de responsabilité*') apply for glasses, whether tinted or not, and whatever the diameter or material of the lens.

- For patients under 18 years old, only organic lenses are reimbursable.
- Until a child's 6<sup>th</sup> birthday all lenses, frames, and other materials are reimbursed without any annual allocation limit.
- From the age of 6 and until the 18<sup>th</sup> birthday, the reimbursement of glasses, frames, and other materials is provided within the limits of an annual maximum allocation.

The reimbursement of tinted lenses is only provided in the following cases:

- Ocular infections: acute conjunctivitis, keratitis, iritis, congenital and nuclear cataracts, retinitis;
- High myopia with photophobia;
- Some photophobias.

The reference prices ('*tarifs de responsabilité*') for lenses before the 18<sup>th</sup> birthday are 66.52 euros for one lens, and 24.54 euros after the 18<sup>th</sup> birthday.

The reference prices for frames are 30.49 euros before the 18<sup>th</sup> birthday, and 2.84 euros after it.

Contact lenses are reimbursed on the basis of an annual lump sum that amounts to 39.48 euros per eye. They are reimbursable in the case of: karatoconus; irregular astigmatism; myopia higher or equal to 8 dioptries; aphakia; anisometropia at 3 dioptries – not correctable by glasses; and Accommodative strabismus.

Miscellaneous supplements are also reimbursed by the insurance fund, e.g. incorporated prism, antiptosis systems, ultraviolet and chromatic filters, iseiconic lenses. Partial occlusion filters, pliable prisms, tand the supplement for goggle frames are reimbursed before the 18<sup>th</sup> birthday.

### **Orthopaedic appliances and other prosthesis (HC.5.2.2)**

Minor orthopaedic appliances are reimbursed up to 65% of reference prices (*'tarifs de responsabilité'*) whereas major therapeutic appliances are reimbursed up to 100% of reference prices. Extra-billings are always user charges.

### **Hearing aids (HC.5.2.3)**

The responsibility tariffs cover:

- The purchase of hearing aids with the necessary accessories,
- The cost of adjustment.

Patients up to 20 years old and patients suffering from blindness and hearing loss are reimbursed at a rate of 65% of the tariff (between 600 and 1,400 Euro).

For patients who are over 20 years old, the hearing aid is reimbursed at a rate of 65% on the basis of a fixed charge of 199.71 Euro.

The maintenance costs are reimbursed at a rate of 65% on the basis of an annual standard allowance of 36.59 Euro.

### **Medico-technical devices, including wheelchairs (HC.5.2.4)**

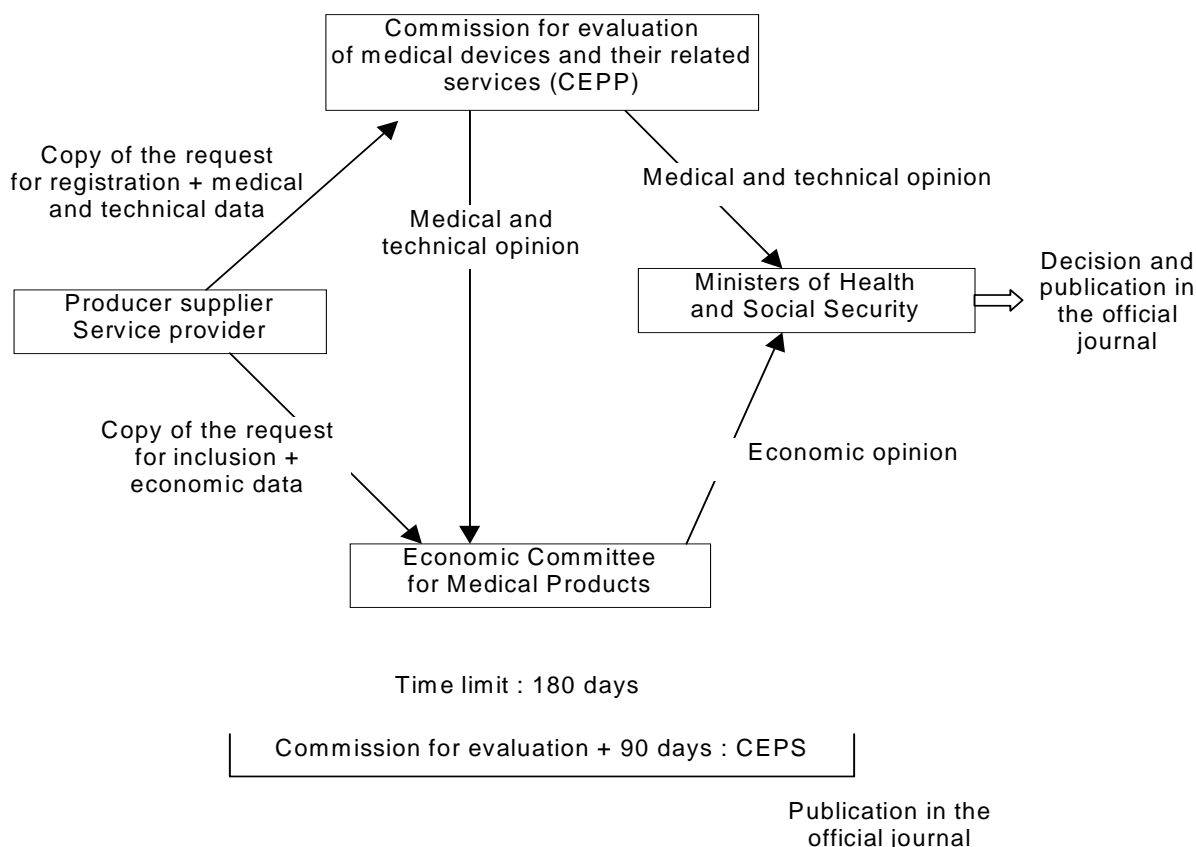
Reimbursement is provided for disabled people who are totally or partially unable to walk, whether this is permanent or temporary in nature, as a result of loss of movement of the lower limbs due to disease, injury, congenital malformation, or ageing.

Charges for wheelchairs vary between 394.60 and 5,187.48 Euro, whilst for other vehicles, they are between 263.83 and 962.20 Euro.

### **All other miscellaneous medical durables (HC.5.2.9)**

Products have to be prescribed and included in the LPP.

**Diagram 2: Decision-making procedures for registration of medical devices**



**Box 2  
The High Health Authority**

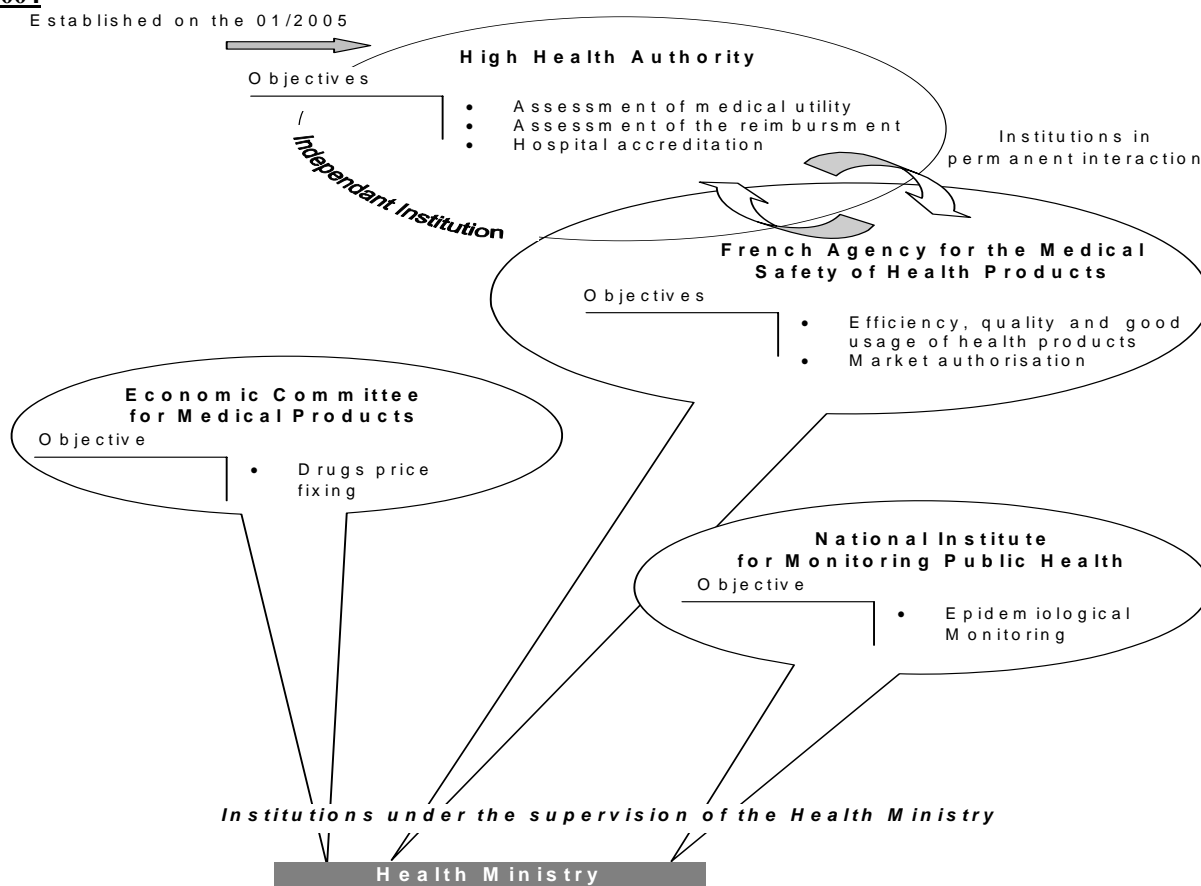
The 'Haute Autorité de Santé' (High Health Authority) was created by the health insurance law of 13 August 2004 as a result of a recommendation of the High Council for the Future of Insurance Funds (Haut Conseil pour l'Avenir de l'Assurance Maladie). It is an independent scientific public authority with legal status.

The High Health Authority's aim is to evaluate the medical usefulness of the whole range of medical procedures, services, and products which are reimbursed by the health insurance fund, and to promote good practice within the French health system. The High Health Authority has five main objectives :

- the drawing up of recommendations on the conditions of reimbursement of health care procedures concerning the treatment of certain diseases, especially long-term illnesses (ALD);
- the contribution by means of its medical and public health expertise, to the validity and relevance of reimbursement-related decision making
- the distribution of guidelines to health care professionals and to the general public,
- the drawing up and implementation of hospital accreditation procedures.

In order to carry out its responsibilities, the High Health Authority works with the French Agency for the Medical Safety of Health Products (AFSSAPS), the National Institute for Monitoring Public Health (INVS), and the French Agency for the Medical Safety of Food Products (AFSSA).

### **Diagram 3: the system created by the Act on Health Insurance of 13 August 2004**



### **Prevention and public health services**

Preventive medicine in France comprises a range of activities such as health monitoring and diagnostics, and is made up of three parts:

- Preventive medicine and screening;
- Specific public health programmes;
- General public health activities.

The CNAMTS has at its disposal a special fund for the financing of prevention activities, the National Fund for Prevention, Education and Health Information (FNPEIS). This fund subsidises primary prevention services, e.g. vaccination campaigns, national and regional health education programmes; secondary prevention services, e.g. genetic screening, and screening for cancer and oral and dental ailments; and tertiary prevention services, e.g. information programmes for patients suffering from long-term diseases.

At the national level, the topics to be included in the prevention programmes are determined in the three-yearly Convention of Objectives and Control negotiated between the CNAMTS and the State. The subjects for the period 2002 to 2005 are:

- Preventative health care of pregnant women and babies;
- Improvement of vaccination coverage;
- Development of oral and dental preventative care;

- Health promotion activities and the screening of all school age children;
- Extension of medical examinations;
- Promotion of cancer screening;
- Prevention of occupational risks;
- The participation of Regional Insurance Funds (CMR) in regional prevention initiatives.

#### ***II.1.12. Maternal and child health, family planning and counselling (HC.6.1.)***

Maternal and child health prevention covers a wide range of health care services, such as :

- Medical, psychological, and social prevention services, health education for future parents, and children;
- Prevention activities and screening for disabilities for children under six years old, and family counselling;
- Observation and inspection of crèches, nurseries and other establishments for children under six as well nurseries' assistants.

There are two levels of administration that recover prevention activities. At national level, a subdivision of the Ministry of Health deals with 'Mother and child and special health care', whilst 'Mother and child protection' (PMI) are dealt with at departmental level. The latter covers:

- Family planning and education, medical and social care of pregnant women, prenatal, prenatal and postnatal counselling, medical and social prevention activities;
- health care, vaccination, and comprehensive medical check-ups for babies;
- activities targeted at various childhood illnesses according to local priorities.

The PMIs provide free health services to pregnant women and children under 6 years old, but the majority of these still go to general practitioners as well as private-sector paediatricians.

##### Neonatal screening

This is a national programme concerning all neonates. Screening tests enable the identification of some genetic diseases such as phenylketonuria, congenital hypothyroidism, congenital hyperplasia of the suprarenals, sickle-cell anaemia, and cystic fibrosis.

##### Dental check-up (BBD)

Dental check-ups are a preventive measure aimed at children between 13 and 18 years of age. It aims to facilitate access to dental care, to improve the state of dental health, and to promote regular dental check-ups. The BBD is entirely free. It includes a buccal and dental examination, a dental X-ray, if necessary, and dental care and hygiene counselling. It is provided by a dentist approved by the health insurance fund, and who have their own practises or who work in health centres.

If necessary, the dentist draws up a personal programme of dental care which is reimbursed by the health insurance fund if the following conditions are fulfilled:

- it concerns maintenance care (scaling, polishing, and fillings), surgical care (extraction), and X-rays, (dentofacial orthopaedic treatment, and dental prosthesis are not included);
- dental care is provided within six months after the complete check-up (BBD), otherwise dental care is reimbursed according to the usual conditions.

#### **II.1.13. School health services (HC.6.2.)**

School health services are the responsibility of the regional chief education officer, whose duties are:

- Medical visits and check-ups;
- Periodical medical examinations,
- Supervision of vaccination;
- Medical supervision of sporting activities;
- Health screening and the coordinated implementation of preventive medicine and health education activities;
- In-depth follow-up of medical check-ups (on request).

The priority programmes concern: screening for and prevention of child obesity; the organisation of the school year; asthma; child and teenage mental problems; health education for young people.

#### **II.1.14. Prevention of communicable diseases (HC.6.3)**

*Vaccination:* According to art. L.3111-1 of the Public Health Code (CSP), “anti-diphtheria vaccination by diphtheria toxoid is compulsory. According to art. L.3111-4, “a person who, in an establishment or organisation, whether public or private, has a professional activity which exposes them to contamination risks must be immunised against hepatitis B, diphtheria, tetanus, and poliomyelitis”. “People who have a professional activity in a medical analysis laboratory must be immunised against typhoid fever.”

The insurance fund reimburses under medical prescription the following vaccinations:

- Compulsory vaccinations for children: BCG anti-tuberculosis vaccination; Anti-diphtheria, anti-tetanus, and anti-poliomyelitis vaccinations.
- Recommended vaccinations for children: measles, mumps, and rubella (German measles); hepatitis B; whooping cough.
- Compulsory vaccinations for health-care professionals: Tetanus; Poliomyelitis; Diphtheria; Hepatitis B ; Typhoid.
- Recommended vaccinations for health-care professionals: Hepatitis A ; Leptospirosis; Rabies.

Some compulsory or recommended vaccines for travelling purposes, e.g. cholera and yellow fever, are not reimbursable.

#### Influenza vaccination

Every year the health insurance fund leads an information campaign to encourage people aged over 65 years old and those suffering from chronic illnesses to have themselves vaccinated against influenza. The vaccination is free of charge.

The long-term illnesses concerned are diabetes (types 1 and 2) cerebrovascular accidents; Bright's disease, neuronal diseases, e.g. muscular dystrophy and epilepsy; cystic fibrosis, heart attacks, respiratory failure, AIDS, haemoglobin diseases.

There are specific conditions for the reimbursement of Prevenar vaccination.

### **II.1.15. *Prevention of non-communicable diseases (HC.6.4)***

The programmes against drug addiction, alcoholism, nicotine addiction, AIDS, etc. are financed by the Health Ministry and through interministerial credits such as those from the Interministerial Mission for the Fight against Drug Addiction (MILDT), which is under the Prime Minister's direction. It organises and co-ordinates action in 17 ministerial departments dealing with the fight against drug and other types of addictions.

#### Drug addiction

The establishments that specialise in the fight against drug addiction are called Specialist Centres for the Health Care for Drug Addicts (CSST). Some provide accommodation, whereas others do not. These centres are responsible for the reception, the advising and the provision of information to drug addicts and their families, the process of withdrawal, and the support of the families. There are three main types of structure : outpatient care centres, care centres with accommodation, and care centres in prison.

The ambulatory care centres provide medical counselling, nursing care, and psychological and social care.

In the care centres with accommodation, drug addicts are offered medical, psychological, social, and educational care.

There are also networks of 'therapeutic apartment', emergency accommodation organisations, and host family networks.

Additional services are being implemented to improve access to syringes and the transmission of advice concerning preventive measures to the population at risk. Since 1987, syringes have been sold at the chemist's without prescription on an 'over the counter' basis, and automatic distributors have been installed.

'Street kits' have been distributed by associations within the framework of preventive action against AIDS and the reduction of the risks among drug addicts. These kits contain two syringes, two disinfected pads, and a condom.

The 'methadone bus' aims to improve access to methadone treatment, to obtain information as to the demand for such treatment, and to take account of the social problems that go with such addiction.

#### Alcoholism

The Centres of Ambulatory Care for Alcoholism (CCAA) are subsidised by the health insurance funds, and aims to provide free health care and social assistance for people with a high level of alcohol consumption or who are alcoholics. These structures are supplemented by various preventive services provided by private or public alcoholism centres.

#### Nicotine addiction

The relevant authorities have established a programme which is based on the recommendations of both the WHO and the World Bank. This programme was legally established by the laws of August 9, 2004, and July 31, 2003, which aim to reduce young people's tobacco consumption, and by the decree of March 5, 2003 on the labelling of tobacco products. The law of August 9, 2004 also allowed the government to ratify the WHO convention against tobacco consumption, which was the first international public health treaty. The administrative, regulative and tax measures are :

- an increase of the price of cigarettes of more than 40%;
- a ban on the sale of tobacco to children under 16 years old;
- a ban on small packets of cigarettes;
- a ban on the advertisement of tobacco products;
- an increase of the fine related to breaking legal tobacco regulation from 75,000 to 100,000 Euro;
- no smoking in public areas.

People in financial difficulty who want to stop smoking can benefit from free drugs and nicotine substitutes. There are also specialised tobacco withdrawal centres for nicotine addicts and people suffering from tobacco consumption-related illnesses.

### Cancer screening

The 'Rendez-vous Santé +' breast cancer screening programme is supported by the Health Ministry, the health insurance funds, the 'Conseils Généraux' (Councils at the department levels), and the League against Cancer charity. It concerns women between 50 and 74 years old, and consists of offering a free mammography once every two years. This is followed by a clinical examination, and is reimbursed at a rate of 100% by the health insurance funds. Breast cancer screening is organised at local level by specialised management organisations which send out invitations to the women concerned.

### Health check-ups

All health insurance contributors and others entitled to do so are offered a medical check-up once every five years. This consists of individual medical examinations, analyses, and tests which take each person's age, gender, lifestyle, and health risk factors into account.

#### ***II.1.16. Occupational health care (HC.6.5)***

The organisation of occupational medicine falls within the domain of private law, and is the responsibility of the Ministry of Labour. Its main objective is the prevention of illness. It does not provide curative health care services, except for emergency care, and does not write prescriptions or authorise periods of sick leave.

In France, this exclusively preventative occupational medicine system enables the health status of employees to be checked and an appropriate adaptation of the workplace to human needs to be provided.

It consists of:

- the determining of fitness for work;
- the monitoring of employees' health;
- the study of the work environment.

Occupational medicine also plays a role in the fight against alcohol and nicotine addiction, cardiovascular disease, and cancer.

All private sector employers have to organise and finance the medical monitoring of their employees. In the public sector, this duty is the responsibility of the preventative health services.

Employees are entitled to a medical check-up when they are first taken on, and to an annual examination or check-up after a period of sick leave of more than 21 days due to an accident at work or occupational illness. Some employees have the right to supplementary medical visits according to their particular situations, whether personal, e.g. pregnant women, or professional, e.g. exposure to certain substances.

#### **II.1.17. All other miscellaneous public health services (HC.6.9)**

The general regulation concerning hygiene rules and other human health protection measures in France is the responsibility of the Council of State and the High Council of Public Hygiene. It is controlled by provisions concerning:

- the prevention of communicable diseases;
- environmental health concerning human dwellings and all other places related to human life;
- the provision of drinking water;
- environmental protection activities;
- drainage, treatment, removal, and utilisation of waste water and refuse;
- the fight against neighbourhood noise and domestically produced atmospheric pollution;
- the preparation, distribution, transport, and preservation of foodstuffs.

### **III. DESCRIPTION OF THE BENEFIT CATALOGUES, THE ACTORS INVOLVED, AND DECISION-MAKING CRITERIA**

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In January 2005, three health benefits catalogues for medical services exist:

- the general fee schedule (*Nomenclature Générale des Actes Professionnels* - NGAP), which specifies the list of medical procedures which are reimbursable when delivered by licensed health professionals in private practice, whether in their own consulting rooms or in private for-profit-hospitals (<http://www.ameli.fr/264/RUB/264/omb.html>);
- the fee schedule for laboratory tests (*Nomenclature des Actes de Biologie Médicale* - NABM), which applies to tests related to outpatient care in private practice, whether in specialists' own consulting rooms or in private hospitals. (Zizine Hubert, 1995, Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (CNAMTS), 2000 and 2005; CEPS and LEEM, 2003) <http://www.ameli.fr/76/RUB/76/omb.html>
- The medical services benefit catalogue is being revised, and a new classification entitled the 'Classification Commune des Actes Médicaux' (CCAM) has been produced and is being adopted in 2005 <http://www.ameli.fr/77/RUB/77/omb.html>.

The basket of reimbursable goods is defined by three lists :

- Two positive lists for drugs:
  1. One for drugs purchased in pharmacies: the list of reimbursable pharmaceuticals (Liste des Spécialités Pharmaceutiques Remboursables aux Assurés Sociaux - LSPRAS);
  2. and one for drugs delivered in hospitals or other institutions: the list of hospital drugs (Liste des spécialités agréées aux collectivités).

And

- The list of reimbursable 'medical devices' and their related services (Liste des Produits et Prestations - LPP), see: <http://www.ameli.fr/225/DOC/1143/enquete.html>.

The following paragraphs present these catalogues in details.

### **General Fee schedule (NGAP)**

The NGAP's structure is mono-axial, and its present structural organisation is not standardised because of the variation of the organisational criteria from one chapter to another. It is made up of the following sections :

- General arrangements;
- Nomenclature of medical procedures which do not use ionising radiation;
- Nomenclature of medical procedures using ionising radiation,
- Nomenclature of medical procedures of vascular radiology and interventional imagery;
- Nomenclature of anatomy and pathological cytology procedures.

The first part of the NGAP contains general information about, for example, the rating of medical procedures, the corresponding key-letters, the fees and additional charges for consultations with specialists, dentists, midwives, and other medical professionals, and specific reimbursement procedures.

The second section, 'Nomenclature of medical procedures which do not use ionising radiation' is divided into sixteen chapters :

1. Traumatic lesion treatment procedures;
2. General tissue-related procedures;
3. Head-related procedures;
4. Cervix-related procedures;
5. Vertebral column and spinal cord-related procedures;
6. Upper limb-related procedures;
7. Thorax-related procedures;
8. Abdomen-related procedures;
9. Urinary system-related procedures;
10. Male genitalia-related procedures;
11. Female genitalia-related procedures;
12. Lower limb-related procedures;
13. Diagnosis and treatment of mental disturbance;
14. Rehabilitation and functional recovery procedures;
15. Miscellaneous;
16. Nursing care.

The 'Nomenclature of medical acts using ionising radiation' has three chapters :

1. X-ray diagnosis;
2. X-ray treatment;
3. Procedures using X-ray elements of flexible sources.

The 'Nomenclature of medical procedures of vascular radiology and interventional imagery' is divided into four chapters :

1. General arrangements;
2. Vascular radiology;
3. Interventional radiology;
4. Invasive, diagnostic, and interventional cardioradiology.

The final section, 'Nomenclature of anatomy and pathological cytology procedures', refers to procedures concerning anatomy and pathological cytology.

A key letter and a coefficient designate all medical procedures. There are thirty-three key letters, with, for example, the key letter 'KC' indicating that the code refers to surgery. These key letters have a value in euros, which is negotiated regularly by the health insurance fund, by doctors' representatives, and by the government. A key letter's value is multiplied by the coefficient preceding it.

**Box 3**  
**Physicians' services: Examples of fee schedule, in January 2005**

Physicians services:

- General practitioners' fees for office consultation: C: €20, detailed consultation (CALD): €26
- General practitioners' fees for home visits: V = €20. There are also extra charges for the travel involved in such visits at night and on Sundays (MD and MDE) – 10 euros and a lump-sum travel allowance - 3.5 euros. According to the good call-out use care agreement of 5 June 2002, when the patient's state of health justifies it, the extra travel charge of 10 Euro which is added to the fee for the visit (20 Euro in the case of a GP) is reimbursed by the health insurance fund. Otherwise, only the actual fee for the visit is reimbursed.
- Specialists' office consultation: CS = €23 for all specialists except psychiatrists, CNPSY = €34.30 for psychiatrists
- Specialists' fees for home visits: VS = €20.58 and VNPSY = €31.25.
- Surgical treatments: Key letter: KC = €2.09, and anaesthesia ARE =
  - Fee of the surgeon for cataract extraction: 100 KCC = €209.
  - Fee of the surgeon for total thyroidectomy: 120 KCC= €250.8
- Doppler ultrasound procedures: Key letter: KE = €1.89,
  - Non-obstetrical diagnostic ultrasound (from 20 to 65);
  - Obstetrical diagnostic ultrasound – obstetrical (from 16 to 60);
  - Other diagnostic ultrasound examinations (from 20 to 60);
- Diagnosis and treatment of mental disorders, Key letter: K=€1.92;
  - Mental tests: coefficients between 2 K (€3.84) and 20 K (€38.4);
  - Treatments: coefficients between 1.5 K (€2.88) and 18 K (€34.56);
  - Electroconvulsive therapy (ECT) or electronarcosis with chemical agents: 8 K (€15.36);
  - ECT under general anaesthesia: 18 K (€34.56).
- Key letter for orthodontic treatment ORT = €2.15, etc.

**Box 3 (continued)**  
**Physicians' services: Examples of fee schedule, in January 2005**

Diagnostic radiology

“Z” is the key letter for radiological examinations. The rate for all radiological monitoring carried out under plaster or resin is increased by 20%, and by 40% for radiographic examination carried out on children under 5 years old. The rate for any other comparative radiography is reduced by 60%.

- Diagnostic radiological procedures on the skeleton (from 1 to 120);
- Diagnostic radiological procedures on the internal organs (from 12 to 90);
- Various examinations - arthrography of wrist 52; lymphography 100; radiographic examination for calculation of bone age 15;
- Examinations using special apparatus:
  - Tomography Z 25,
  - Radiocinematography or X-ray video recorder Z 25;
  - Image intensifier Z14.50;
  - Computed tomography (Z105.19 – Z 62.50).
- Vascular radiology - the rate is based on a lump sum – K, KC, Z:
  - Arteriography of the head K150 + Z300 + ARE30;
  - Abdominal aortography K75 + Z120 + ARE30;
  - Phlebography of the lower limbs K100 + Z90 + ARE30.

Nuclear magnetic resonance imagery:

The reimbursement for a nuclear magnetic resonance imagery examination is obtained by the addition of both a fixed rate and a technical lump sum (C3 if the examination is carried out by a general practitioner, and CS 3 if the examination is carried out by a specialist). The rate for 2003 was between 206.57 and 244.68 Euro according to the power of the echotomograph (ultrasound scan).

**Box 4**  
**Dentists' services: Examples of fee schedule, January 2005**

- Key letter for conservation care: SC=€2.41
  - Permanent dental filling:
    - simple cavity: 6 SC (€14.46) or 7 SC (€16.87) for the permanent teeth of children under 13 years old);
    - coronal and radicular pulpectomy with filling of canals and care resulting from gangrene of the pulp – molar group: 25 SC (€60.25) or 30 SC (€72.30).
  - Dental hygiene and treatment of periodontal diseases:
    - wire ligatures for periodontal diseases: 8 SC (€19.28),
    - retention splint prosthesis: 70 SC (€168,70).
- Key letter for surgical dental care: KC or KCC (for stomatologists), DC for dentists, with KC = DC = €2.09:
  - Tooth extraction:
    - permanent tooth: 10 KC (€20,9);
    - wisdom tooth: 40 KC (€16.4);
    - surgical extraction of an impacted permanent tooth, treatment of the root, replantation, splinting of two teeth: 150 KC (€361.5).
  - Treatment of osseous and gingival lesions:
    - Regularisation of alveolar crest with gingival suture: 15 KC (€36.15);
    - Surgical excision of a cyst in the maxilla: 50 KC (€120.5);
  - Pre-prosthetic surgery (immediate prosthesis is not included; pre-operation reimbursement agreement required):
    - Buccal vestibule: 40 KCC (€16.4);
    - Roof of the mouth with section of mylohyoid lines: 60 KCC (€144.6).
- Key letter for dental prosthesis: SPR = €2.51
  - Joint dental prosthesis:
    - Tooth crown (metal casting technique): 50 SPR (€125.5);
    - Dowell crown: 35 SPR (€87.85).
  - Removable denture:
    - Dental prosthesis – from 1 to 3 teeth: 30 SPR (€75.3), for 14 teeth: 85 SPR (€213.35).
- Other fees for dental and maxillofacial surgeons' fees:
  - consultation: C = €20, CS = €22.87;
  - visit: V = €16.77, VS=€20.58 ;
  - treatment of dentofacial ortopedics : TO 2.15 euros;
  - Key letter for radiology: Z= €1.33;
  - Key letter for other dental services : D 1.92 euros. Aude

#### Box 4

#### Nurses and other health professionals' services: Examples of fee schedule, January 2005

##### Nurses' services

- Key letter for nurses' fees for home care: AIS = €2.40 euros or AMI = €2.90 euros), lump sum travel allowance – (IFD = 2 euros); nursing care plans – (DI = 10 euros). There are also extra charges for call-outs at night and on Sundays, as well as a travel allowance. These procedures are rated between 1 (e.g. for an intramuscular injection) and 16 (for nursing care at home).
- Nursing care at home for temporarily or permanently dependent patients (regardless of age):
  - Key letter for the elaboration of therapeutic nursing plans: DI= €10. Elaboration of the first plan: 1.5 DI (€15), and for the following: 1 DI (€10);
  - Nursing care visits (half-hour sessions): 3 AIS (€7.2);
  - The implementation of a personalised assistance programme: 3.1 AIS (€7.44);
  - Weekly sessions of medical monitoring and prevention (per half-hour session): 4 AIS (€9.6).
  - Home care for sick person requiring constant observation and regular nursing care, including hygiene care: 13 AIS / 16 AIS per 6-hour period (day/night).
- Monitoring and observation of the patient at home :
  - Administration and monitoring of oral treatment for patients with psychiatric disorders or the implementation of treatment for insulin-dependent diabetics: 1 AIS.
- Specialised nursing care:
  - Treatment at home of patients suffering from cancer or immunodeficiency: from 1.5 AIS (IV injection) to 15 AIS (parenteral treatments > 1 hour);
  - Treatment at home by antibiotic transfusion of a patient suffering from cystic fibrosis and requiring continuous monitoring: 15 AIS (€36);
  - Treatment at home of a patient under insulin treatment: from 1 AIS to 4 AIS.

##### Physiotherapists' fees:

- Key letter for medical treatment carried out in their treatment rooms or in the patient's home: AMK = €2.04; lump sum travel allowance of 2 euros, and extra charges for call-outs at night (€1.15) and on Sundays (€7.62), as well as a travel allowance.

##### Speech therapists' services

- Key letter for speech therapists' fees: AMO = €2.37, and the lump sum travel allowance is €1.52.

##### Orthoptists' services

- Key letter for orthoptists' fees: AMY= €2.38, and the lump sum travel allowance is 1.45 euros (plus extra call-out charges at night and on Sundays). AUde

### Reimbursement by assimilation

When a patient is affected by an unusual illness which justifies a medical procedure which is not mentioned in the NGAP, this procedure can, exceptionally, be put into a similar category with the same coefficient that is included in the NGAP. The reimbursement for this procedure is dependant upon the favourable decision of the CNAMTS' medical services and the completion of formalities concerning the prior authorisation.

### Prior authorisation

In order that some medical procedures, e.g. dentofacial orthopaedic treatments, are reimbursed by the health insurance funds, a prior agreement is required on the part of the funds.

Since its creation, the 'Nomenclature' has been the responsibility of the NGAP Permanent Commission.

At the request of the Ministries of Health and Social Security, the health insurance funds, the most representative of the professional bodies, or the majority of its members, the Permanent Commission can make proposals concerning (Zizine Hubert, 1995):

- the inclusion in the nomenclature and the provisional charging rate of medical procedures which bring about an improvement of the medical service or a cost-containment of treatment;
- the interpretation of the NGAP nomenclature.

The Permanent Commission is a joint commission which has, in addition to the chairman, who is appointed by the social security minister, 7 or 8 representatives of interested professional groups, who are nominated by the minister on the recommendation of the trades unions. Their number (7 or 8) varies according to whether the issues under discussion concern doctors, dentists, midwives, nurses, physiotherapists, speech therapists, orthoptists, or chiropodists.

Parity of representation is assured by 7 or 8 members – the director and the medical examiner of each of the three national insurance funds, one person chosen for his economic expertise, and, if needed, another person, chosen for his expertise within the field of health. The members are appointed for a maximum period of three years. Administrative services are provided by the CNAMTS.

The representatives of each of the professional organisations concerned can appoint an expert for each issue. This person can be heard by the Commission's reporter (spokesperson), but cannot take part in meetings.

Not all the requests made to the Commission are necessarily examined. The proposals are usually voted upon within 3 months after the inclusion of the request on the agenda.

### **Nomenclature of Medical Biology Procedures (NABM)**

Before 2004, the opinion of the Permanent Commission of the NABM was a necessary prerequisite to the inclusion of medical procedures in the NBAM in the case of medical biology procedures. This commissions had equal representation of representatives of interested professions, on the one hand, and, on the other hand, of representatives of the health insurance funds and qualified people. Furthermore, since 2004, new procedures have to be assessed by ANAES/High Health Authority.

Since the Act of 13 August 2004, UNCAM has decided which procedures should be included on the list, such decisions being taken in the light of advice of a High Health Authority special commission.

The Nomenclature of Medical Biology Procedures (NABM) was created by the law of April 3, 1985, and has eighteen chapters :

5. General arrangements;
6. Anatomy and pathological cytology procedures;
7. Cytogenetics procedures;
8. Human-assisted reproduction;
9. Spermatology;
10. Haematology;
11. Microbiology;
12. Immunology;
13. Virology;
14. Functional tests;
15. Hormonology;
16. Enzymology;
17. Proteins – Tumour markers – Vitamins;
18. Biochemistry;
19. Toxic medicines;
20. Isotopic marker procedures;
21. Tests for gene amplification and molecular hybridisation (prenatal diagnosis is excluded);
22. Prenatal diagnosis.

**Box 4**  
**Examples of fee schedule, January 2005**

- Anatomy and pathological cytology procedures (key letter: P = €0.28):
  - histopathological diagnosis by embedding and sectioning of bioptic samples: P100;
  - histopathological diagnosis by embedding and sectioning of tiered bioptic samples P130;
  - histopathological diagnosis by embedding and sectioning of a surgical patch P120;
  - histopathological diagnosis by embedding and sectioning of specimens coming from resection or from an endoscopic or endocavitary curettage P120;
  - histopathological diagnosis by embedding and sectioning of a complex surgical patch P220;
  - extemporaneous examination P300;
  - gynaecological cytopathological diagnosis P55;
  - cytopathological diagnostics on liquids, extravasations, discharges, lavages, expectorations, vacuum extractions, brushings, and scrapings P100;
  - cytopathological diagnosis on ganglionic and tumorous punctures, and organ puncture P120;
  - cytopathological diagnosis of a specimen obtained by puncture P130;
  - immunohistochemical examination of sections P200, P300.
- Medical biology procedures (key letter: B = €0.27):
  - Cytogenetics (B40 to B1300);
  - Medical procreation assistance (B150 to B2800);
  - Spermiology (B45 to B280);
  - Haematology (B5 to B300);
  - Microbiology (B10 to B500);
  - Immunology (B20 to B700);
  - Virology (B20 to B1200);
  - Screening for HIV (B300) and hepatitis C (B200-B400),
  - Functional tests (B15 to B145);
  - Hormonology (B50 to B145);
  - Enzymology (B20 to B75);
  - Proteins – Tumour markers – Vitamins (B10 to B220);
  - Biochemistry (B5 to B300);
  - Drugs - Poisons (B35 to B300);
  - Gene amplification and molecular hybridisation (excluding prenatal diagnosis) (B60 to B400);
  - Prenatal diagnosis (B100 to B1500).

## The Common Classification of Medical Procedures (CCAM)

In 1996 the Pole of Expertise and National Reference of Health Nomenclatures (PERNNS), the Hospitalisation and Health Care Organisation Directorate (DHOS), the CNAMTS 'Nomenclature Section' of, and the scientific societies launched a project for the establishment of one single new nomenclature, the Common Classification of Medical Procedures (CCAM), which will replace the two existing medical activity charging systems, CDAM<sup>1</sup> and NGAP. Its two main objectives are the drawing-up of 'labels' and the hierarchical organisation of medical procedures. This work is being carried out by scientific societies and about 1,500 experts.

The CCAM rather lengthy developmental process is currently being implemented. At this stage, the CCAM only specifies technical procedures, such as diagnosis, surgery, radiology performed by physicians. This 'classification' is not, as yet, used in respect of physicians' consultations or procedures carried out by other health care professionals. The positive list is available for dentists, but the dentists' fees are still regulated by the NGAP.

The inclusion of medical procedures in the CCAM is dependant upon the obtaining of the opinion of the National Agency for Accreditation and Evaluation of Health Care (ANAES), which has been transformed into the High Health Authority (Act of 13 August 2004, see above page 13). ANAES used to assess procedures to advise on whether they should be included in the CCAM and, if so, under what conditions. The advice takes account of the effectiveness and/or safety of these procedures, and the conditions under which they should be performed.

The method proposed by the ANAES for advising on CCAM procedures was based on:

- scientific data on the effectiveness and/or safety of the procedures;
- comparisons with procedures included in other countries' nomenclatures;
- the opinion of professionals, obtained by means of by a postal survey;
- the opinion of professionals meeting together as a working group.

This information is examined by a group of experts which submits the report to the ANAES scientific committee. There are four level of scientific evidence: (1) High-powered randomised controlled trials, meta-analyses, and analyses of decisions; (2) Low-powered randomised controlled trials, or non-randomised trials, and cohort studies; (3) Case-control studies; (4) Retrospective studies, case series, descriptive epidemiological studies, and controlled trials with bias.

Comparisons with procedures included in four other countries' nomenclatures are taken into account: the United States (Current Procedural Terminology), Australia (Medicare Benefits Schedule Book), Belgium (Nomenclature of Health Care Services), and Switzerland (list of 160 procedures subject to special reimbursement conditions).

A special commission of the High Health Authority has been responsible for this assessment since January 2005.

The CCAM is fully comprehensive in content as it contains details of all medical procedures, even those that are not reimbursable (<http://www.ameli.fr/77/DOC/83/enquete.html>). Each procedure corresponds to only one label and one code, so there is no ambiguity, and it is easy to use. The classification is according to 'anatomic classification' and according to specialities. There are seventeen chapters :

### 1. Nervous system,

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<sup>1</sup> CDAM (Catalogue des actes médicaux). This catalogue was created in 1985 to give a rating to medical procedures in hospitals in the PMSI scheme (Hospital procedures computer system based on the creation of a DRG classification). Until now, this schedule has been used to classify hospital stays in French DRGs and to calculate "reference" costs for each DRG. Until 2005, public hospitals were paid on a global budget basis and procedures in private-for-profit hospitals were paid on a per diem basis for "general services" and on a fee-for-service basis for specialists' services. CDAM was thus not used to price hospital services.

2. Eye and adnexa of the eye,
3. Ears,
4. Cardiac and vascular system,
5. Immune system,
6. Respiratory system,
7. Digestive system,
8. Urinary and genital system,
9. Pregnancy procedures,
10. Endocrine system and metabolism,
11. Osteoarticular and muscular system of the head,
12. Osteoarticular and muscular system of the neck and the trunk,
13. Osteoarticular and muscular system of the upper limbs,
14. Osteoarticular and muscular system of the lower limbs,
15. Osteoarticular and muscular system of the body,
16. Tegumentary system,
17. Procedures without 'localisation'.

The CCAM is based on the rule of procedural totality. Each label implicitly contains all the operations necessary for the performance of the medical procedure.

## **Positive lists of drugs**

The preliminary consultation procedures for the reimbursement of drugs are undertaken by the Transparency Commission. These consultation procedures are compulsory, in accordance with a decree in Council of State .

The composition of the Transparency commission is firmly orientated towards technical expertise. Its new composition, defined by the decree of September 26, 2003, is the following:

- 20 members have voting rights. They are appointed by the ministers of health and of social security for a period of three years (a term of office which can be renewed twice): a chairman; two deputy chairmen and 17 members chosen on account of their scientific expertise.
- 8 members have a consultative role: the Directors of three directorates of the Ministry of Health, the Director of the AFSSAPS, the directors of the three main sickness funds and one representative of manufacturers' unions.

The Transparency Commission assesses the therapeutic value of each drug (*service médical rendu* – SMR) according to five criteria (article R163-18 of the SSC):

- the effectiveness of the drug and its possible side effects,
- its place in the therapeutic process, in relation to the alternative treatments available,
- the seriousness of the condition in question,

- the curative, preventive, or symptomatic properties of the drug,
- its importance in terms of public health.

The SMR is evaluated for each indication on a five-level scale : it can be classed as ‘major’, ‘considerable’, ‘moderate’, ‘low’, or ‘insufficient’. The level of MSR, together with the seriousness of the disease treated, should determine the reimbursement rate for each medicine.

The Transparency Commission also assesses the therapeutic advantage of each new product, by comparison with existing drugs in the same therapeutic area. The assessed “therapeutic advantage” ranges from ‘major therapeutic advance’ to ‘no advantage’ on a five-level scale. This assessment is very important for price negotiations conducted by the Economic Committee on Health Products (CEPS).

The CEPS is composed of representatives from the Directorate of Social Security, the Directorate-General of Health, the Directorate-General for Competition, Consumption and Control of Fraud, and the Directorate-General for Industry, Technology, Information and Postal Services, as well as a representative from the three main health insurance funds.

Inclusion on the positive list lasts for 5 years, but the Transparency Commission can, at any time, take steps to re-assess the ‘therapeutic value’ (SMR) if there are changes in the therapeutic standards.

The process for the inclusion in the list of hospital drugs (agrément aux collectivités) is generally shorter since hospital drugs prices are free. However, since 2004, costly innovative drugs used in hospitals will be subject to price regulation (Paris, 2004).

Moreover, the decree of 15 June 2004, specifies the regulation concerning drugs sold by hospital pharmacies with internal use (Pharmacie à usage intérieur – PUI). The reimbursement of these so-called retroceded drugs by the health insurance funds depends on their inscription in the retrocession list ([www.sante.gouv.fr](http://www.sante.gouv.fr)). They can be sold only at pharmacies with internal use, to non hospitalised patients. The registration criteria for this list are:

- restraints of distribution or prescription;
- supplying security;
- the necessity of making a particular follow-up of the prescription.
- Types of drugs in the retroceded list:
- drugs with temporary use authorisation (ATU) not classified in hospital reserve;
- imported drugs, not classified in hospital reserve;
- hospital provision (any drugs, except products of genic or cellular therapy), prepared according to the indications of the pharmacopoeia, because of the shortage of appropriated drugs;
- hospital masterful provisions if there is no available and adapted drugs.

The “Liste des spécialités pharmaceutiques remboursables aux assurés sociaux” has eighteen chapters:

- cardiovascular system drugs;
- gastrointestinal system drugs;
- analgesics and anti-inflammatory drugs;
- nervous system drugs;
- hormonal drugs;
- respiratory system drugs;

- anti infection drugs;
- anti-tumour drugs;
- immunosuppressants;
- general anaesthetics;
- curariforms;
- minerals;
- vitamins;
- dietetic drugs;
- anti-poison drugs;
- dermatological drugs;
- topical drugs for ophthalmic application;
- topical drugs for optical application;
- vulva-vaginal drugs;
- diagnostic agents;
- perfusion liquids and vesicle irrigation solutions;
- substitutes and blood derivatives;
- others.

### **The list of medical devices and their related services (LPP)**

The preliminary consultation procedures for the reimbursement of medical devices are undertaken by the Commission for the Assessment of devices and related services (Commission d'Évaluation des Produits et Prestations- CEPP). These consultation procedures are compulsory, in accordance with the law concerning 'medical devices'.

The CEPP is made up of scientific experts as well as representatives of the health insurance organisations and representatives of producers and distributors. It is under the supervision of the ministries of health and social security.

The members of the commission are:

- A chairman and deputy chairman appointed by the ministers of health and of social security;
- The social security director, the general health director, and the director of the French Agency for the Medical Safety of Health Products (AFSSAPS);
- Fourteen members from different institutions, e.g. doctors' representatives, representatives of the CNAMTS, and representatives of the manufacturers of medical products.

The CEPP's opinion includes:

- the description of the product or service;
- the assessment of the 'medical service rendered' (SMR) For inscription on the Liste des Produits et Prestations Remboursables (LPP) there are only two possible forms of the SMR – presence or absence of improvement in the 'service rendered';
- if necessary, the Commission establishes the therapeutic and diagnostic criteria for registration on the list for reimbursement;

- the types of prescription and use of the medical goods and services which depend on reimbursement;
- the trademark or brand name of medical products accepted by the Commission;
- additional assessments necessary for the revaluation of the SMR which should be presented whenever inclusion on the list is renewed;
- a comparison of the SMR with other similar goods and services already on the list or, if necessary, with therapeutic alternatives;
- the assessment of the number of patients experiencing the indications of which the Commission estimates that registration is justified according to available epidemiological data;
- the revaluation of the SMR whenever inclusion on the list is renewed.

The list of reimbursable devices and related services is organised into four sections, each of which contains several chapters (<http://www.ameli.fr/225/DOC/1143/enquete.html>):

- Medical products for treatment and first aid, dietetic food, and bandages :
  - medical products for the treatment of specific illnesses;
  - medical products for first aid and home nursing for the disabled;
  - bandages and retention materials;
- Orthosis and external prosthesis :
  - Orthosis;
  - Medical optics;
  - Electronic hearing aids;
  - External prosthesis (non-orthopaedic);
  - Ocular and facial prosthesis;
  - Pedorthosis;
  - Orthoprosthesis;
  - Prosthetic and orthopaedic appliances.
- Medical appliances for implantations, implants, and tissue grafts :
  - medical implantation appliances which do not contain biological derivatives;
  - medical implantation appliances which contain animal derivatives;
  - tissue grafts of human origin;
  - active implants.
- Vehicles for the disabled.

**Box 6**  
**Examples of reference prices at January 2005:**

Other medical non-durables

- Bandages and retaining materials:
  - Sterile bandages – responsibility tariff of up to 140.25 euros;
  - Bandages (sterile or not) – responsibility tariff of up to 30.49 euros;
  - Purified bandages – responsibility tariff of up to 8.99 euros;
  - Retaining and vascular compression materials – responsibility tariff of up to 6.46 euros.
  
- Nutrition or rehydration products and materials for administering medicine:
  - Gluten-free food - the reimbursement rate is between 33.54 euros a month for children aged 9 and under, and 45.73 euros a month thereafter;
  - Medical products and nutriments for enteral nutrition at home - the responsibility tariff is up to 83.24 euros.

Orthosis (minor orthopaedic appliances)

- Truss – reference prices of between 2 and 46.50 euros;
- Plantar orthosis - reference prices of between 12.94 and 27.43 euros;
- Heel support - reference prices of 43.94 euros;
- Elastic orthosis for the immobilisation of limbs – reference prices of between 1.32 and 42.50 euros;
- Abdominal belts and orthopaedic corsets of reinforced fabric - reference prices of between 3.35 and 102.29 euros;
- Cervical collars – reference prices of between 9.25 and 18.77 euros;
- Standard therapeutic shoes - reference prices of between 30.49 and 71.65 euros;
- Standard non-therapeutic shoes - reference prices of 35.67 euros;
- Pressure garments for badly-burned patients - reference prices of between 7.64 and 165.05 euros.

External non-orthopaedic prostheses:

- Breast prosthesis - reference prices of between 2.54 and 69.75 euros;
- Trachea cannulas - reference prices of between 9.77 and 280.63 euros;
- Transtympanic aerators - reference prices of between 7.77 and 12.81 euros;
- Vocal prostheses - reference prices of between 7.32 and 476.07 euros;
- Respiratory prostheses for tracheotomy - reference prices of between 1.26 and 428.99 euros;

Ocular and facial prostheses:

- Ocular prostheses - reference prices of between 30.29 and 720.64 euros;
- Facial prosthesis – (subject to a detailed quote).

Podo-orthoses:

- Orthopaedic shoes (custom-made) - reference prices of between 348.76 and 654.65 euros.

**Box 6 (Suite)**

Orthoprotheses and external protheses:

- Upper limb appliances - reference prices of up to 208.03 euros;
  - Lower limb appliances - reference prices of up to 4,392.43 euros;
- Appliances for the trunk - reference prices of up to 1,620.17 euros.

Medical equipment for the treatment of respiratory and otorhinolaryngology diseases :

- Aerosol generating equipment (the responsibility tariff is up to 20 euros);
- Medical equipment for the treatment of respiratory insufficiency and associated services - the reimbursement is provided on the basis of a weekly allowance of between 50 and 216.48 euros.
- Medical equipment for perfusion at home - the reference price is up to 2,980.38 euros.
- Medical equipment for self-medication and self-monitoring - the reference price is up to 503.08 euros.
- Medical equipment for the treatment and maintenance of the musculoskeletal system - the reference price is up to 123 euros.

**IV. TABLE : REIMBURSABLE HEALTH CARE GOODS AND SERVICES BY FUNCTIONAL CATEGORIES**

	General Benefit Regulation  (Before 2004)  Now	General Fee Schedule  NGAP  (Will be replace by CCAM)	Positive list of Medical Biology Procedures  NABM	Positive lists of drugs LSAC, ATU, Retrocession, LSPR	List of medical devices and their related services LPP	Implicitly	Excluded
<b>HC.1 Curative care services</b>							
<b>HC.1.1 In-patient curative care</b>							
Public and private non-for-profit hospitals	(?) Order			LSAC+ATU		X	
Private-for-profit hospitals	(Order) UNCAM decision Order	X	X	LSAC+ATU	LPP		
<b>HC.1.2 Day-patient curative care</b>							
Public and private non-for-profit hospitals	Order			LSAC+ATU		X	
- services							
- drugs & devices							

Private-for-profit hospitals - services  - drugs & devices	(Order) UNCAM decision  Order	X	X	LSAC+ATU	LPP		
<b>Outpatient hospital care</b> For all types of hospitals: - services  - drugs & devices	(Order) UNCAM decision  Order	X	X	LSAC+ATU+ Retrocession	LPP		
<b>HC.1.3 Out-patient curative care</b>							
HC.1.3.1 Basic medical and diagnostic services	(Order) UNCAM decision	70%					
HC.1.3.2 Out-patient dental care	(Order) UNCAM decision	70%					Temporary teeth, prefabricated crowns or dowell crowns, and partially-covered crowns.
HC.1.3.3 All other specialised health care  - Nurses, physiotherapists, orthoptists, speech thearpists' services	(Order) UNCAM decision	65%					
HC.1.3.9 All other out-patient curative care							
<b>HC.1.4 Services of curative home care</b>  - Physicians' services  - Nurses' services  - Physiotherapists' services	(Order) UNCAM decision	70%  60%  60%					
<b>HC.2 Services of rehabilitative care</b>							
<b>HC.2.1 In-patient rehabilitative care</b>							
<b>HC.2.2 Day cases of rehabilitative care</b>							
<b>HC.2.3 Out-patient rehabilitative care</b>							
<b>HC.2.4 Services of rehabilitative home care</b>		60%					

<b>HC.3 Services of long-term nursing care</b>							
<b>HC.3.1 Long-term in-patient nursing care</b>							Nursing care which exceeds a total of 5 out of 12 months are not reimbursable by health insurance funds
<b>HC.3.2 Day cases of long-term nursing care</b>							
<b>HC.3.3 Long-term nursing care: home care</b> <ul style="list-style-type: none"> <li>- Nurses' services</li> <li>- Palliative services</li> </ul>	(Order) UNCAM decision  R 162-1-10 of SSC	<b>NGAP</b>					
<b>HC.4 Ancillary health care services</b>							
<b>HC.4.1 Medical analysis laboratory</b> <ul style="list-style-type: none"> <li>- Anatomy and pathological cytology procedures :</li> <li>- Medical biology procedures :</li> </ul>	(Order) UNCAM decision		70%  60%  100% for HIV and Hepatitis C screening				
<b>HC.4.2 Diagnostic imaging</b> <ul style="list-style-type: none"> <li>- Diagnostic radiology</li> <li>- Diagnostics procedures:</li> <li>- Nuclear magnetic resonance imagery:</li> </ul>	(Order) UNCAM decision						
<b>HC.4.3 Patient transport and emergency rescue</b>		<b>65%</b>					
<b>HC.4.9 All other miscellaneous ancillary services</b> <ul style="list-style-type: none"> <li>- Spa treatments</li> </ul>		<b>70%</b> <b>70%</b> <b>65%</b> <b>65%</b> <b>65%</b> <b>80%</b>					
<b>HC.5 Medical goods dispensed to out-patients</b>							
<b>HC.5.1 Pharmaceuticals and</b>							

<b>other medical non-durables</b>							
<b>HC.5.1.1 Prescribed medicines</b>	Order			35%, 65%, 100%			
<b>HC.5.1.2 Over-the-counter medicines</b>							
<b>HC.5.1.3 Other medical non-durables</b>	Order				65% of the responsibility tariff		
<b>HC.5.2 Therapeutic appliances and other medical durables</b>	Order						
<b>HC.5.2.1 Glasses and other optical products</b>	Order				65%		
<b>HC.5.2.2 Orthopaedic appliances and other prosthesis</b>	Order				65% for Minor orthopaedic appliances 100% for Major orthopaedic appliances		
<b>HC.5.2.3 Hearing aids</b>	Order				65%		
<b>HC.5.2.4 Medico-technical devices, including wheelchairs</b>	Order				100%		
<b>HC.5.2.9 All other miscellaneous medical durables</b>	Order				65%		
<b>HC.6 Prevention and public health services</b>							
<b>HC.6.1 Mother and child health; family planning and counselling</b>  (Contraception, sexual and emotional relationships, family problems, abortion, HIV screening.)	(?)				100%		
<b>HC.6.2 School health services</b>							
<b>HC.6.3 Prevention of communicable diseases</b>  <i>Compulsory vaccinations for children</i>  <i>Recommended vaccinations for children</i>  <i>Compulsory vaccinations for health-care professionals</i>  <i>Recommended vaccinations for health-care professionals</i>  <i>Influenza vaccination is free for people aged 65 and over and for those suffering from long-term illnesses. In all other cases, influenza vaccine is not reimbursed.</i>					100% 65% 100% for children under 13 years old 65% 65%		Compulsory or recommended vaccines for travelling purposes, e.g. cholera and yellow fever, are not reimbursable.
<b>HC.6.4 Prevention of non-communicable diseases</b>							

<p>Programmes concerning: drug addiction; alcoholism; nicotine addiction; cancer screening; Health education; safe sex; dental hygiene; health check-ups; influenza vaccination.</p> <p>Consultations in physicians' practices or at a hospital are reimbursed at a rate of 70%, whilst, services provided in specialist drug addiction care centres (CSST), out-patient alcoholism centres (CCAA), and centres to help people stop smoking are free.</p>							
<p><b>HC.6.5 Occupational health care</b></p> <p>Medical check-up for all employees, supplementary medical visits for some employees according to their personal (e.g. pregnant women), or professional (e.g. exposure to certain substances) situations.</p>						<p><b>100%</b></p> <p><b>mais pris en charge par l'employeur</b></p>	
<p><b>HC.6.9 All other miscellaneous public health services</b></p>							

## Catalogue : type of document, actors and contents

	General Benefit regulation	NGAP (will be replaced by CCAM)	NABM	Positive lists of drugs LSAC, ATU, Retrocession, LSPR	
<b>Legal status: law, decree, etc.</b>	Law	<u>Before 2004:</u> Order <u>Now:</u> UNCAM decisions	<u>Before 2004:</u> Order <u>Now:</u> UNCAM decisions	Order	Order
<b>Decision-maker</b>	Parliament	<u>Before 2004:</u> Ministers of health and social security, on the advise of the Permanent commission of the NGAP  <u>Now:</u> UNCAM, on the advise of a commission of the High Health Authority and with the advise of the National Union of complementary insurers. Ministries of health keeps the right to include/exclude procedures for public health matters.	<u>Before 2004:</u> Ministers of health and social security, on the advise of the Permanent commission of the NGAP  <u>Now:</u> UNCAM, on the advise of a commission of the High Health Authority and with the advise of the National Union of complementary insurers. Ministries of health keeps the right to include/exclude procedures for public health matters.	Ministers of health and social security, on the advise of the Transparency Commission (part of the High Health Authority since 2004) after:  - Licensing by AFSSAPS;  - Price negotiation with the Economic Committee for Medical Products (CEPS) is	Ministers of health and social security, on the advise of the Commission for assessment of medical devices and their related services (part of the High Health Authority since 2004), after  - licensing by(AFSSAPS; - price negotiation with the CEPS
<b>Original purpose – entitlements, reimbursement, target-setting</b>	Reimbursement  Exemption from co-payments	Positive list  Fee schedule	Positive list  Fee schedule	Positive list  Prices or reference prices	Positive list  Reference prices
<b>Positive/Negative definition of benefits</b>	P	P	P	P	P
<b>Degree of explicitness: 1 “all necessary”, 2 “areas of care”, 3 “items”</b>	3  (except in-patient care : 1)	3	3	3	3
<b>If itemised: goods/procedures only; linked to indications</b>	Mainly - goods/procedures;  Linked to indications	Procedures, sometimes linked to indications	Procedures, rarely linked to indications	Pharmaceutical products, linked to indications	Goods linked to indications
<b>Updating</b>		Regularly  (deep change in progress with the CCAM)	Regularly	Regularly	Regularly

**Criteria used for defining benefits**

<b>Need</b>	X	X	X	X
<b>Costs</b>				
<b>Effectiveness</b>				
<b>Cost-effectiveness</b>			(X)	X
<b>Budget</b>				
<b>Other</b>				

## V. DISCUSSION

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The report faces a number of limitations, which may influence the findings.

First, the study was carried out in a period of changes related to the re- definition of the medical procedures for both inpatient and outpatient care. This will make some statements in the previous catalogue obsolete. Furthermore, the introduction of the new CCAM catalogue has been postponed several times due to conflicts of interest between health professionals, especially those between the physicians' unions and the health insurance funds. The 'payment – practice' relationship is at the core strategy of any health policy. The catalogue deals with the two issues of the remuneration of health-care professionals and state regulation.

Secondly, the recent reform of health insurance (Act on health insurance of 13 August 2004) is influencing all the actors involved in the definition of the benefit catalogue and thus the decision criteria. The High health Authority (Haute Autorité de santé), for instance, will have considerable powers. In the same time, the National Union of Health Insurance Funds (Union Nationale des caisses d'Assurance Maladie), which is a 'self-governing body' is also playing a important role in the drawing up of the positive lists of procedures, pharmaceuticals and medical devices. However, the ministers of health and social security still retain their right to reject the UNCAM's decisions. The question could be asked as to whether the change regarding the delegation of the task of drawing up benefit catalogues to a self-governing body, as, for example, is the case in Germany, is fully effective. It is too early to assess the consequences that these new regulations will bring about, but it could be supposed that it may well be a case of "*plus ça change, plus c'est la même chose*" as both the French government and doctors have always played a major role in the health care decision-making process.

Third, the French system offers a mix between explicit regulation (ER) - for ambulatory care, pharmaceuticals and medical devices, dental care etc., with benefit catalogue and positive lists - and implicit regulation (IR) for inpatient care (Gibis and al. 2004). On the whole, the 'package' of health care and services covered is comprehensive and wide-ranging even though the 'extra billing' is rather high for certain types of goods and services. As a consequence of the implicitness of the coverage with particular respect to inpatient care, we have noted some differences between principles and practice: signifying that not all services benefit from the same effectiveness of coverage. The interviews performed at the Ministry of health confirmed this finding.

Similar results were observed when examining the principles regarding the definition of the health basket and their implementation in respect of pharmaceuticals. The reassessment of the 'medical service rendered' (SMR) therapeutic value of numerous products followed the decree of October 1999. Among the 4,490 products reviewed by the Transparency Commission, 2,815 products (62.7 %) have a 'major' or 'important' therapeutic value, 840 (18.7%) have a 'moderate' or 'low' therapeutic value, and 835 (18.6%) have an 'insufficient' therapeutic value (<http://www.afssaps.sante.fr>). Drugs with an insufficient SMR should no longer be on the positive list. However, the delisting of so many products was politically problematic and did not begin in earnest until 2003. Before this date, several price cuts and decreases in reimbursement rates had been implemented. In 2001, medicines with an insufficient SMR still represented 7.3% of payments by the health insurance funds, and 20.3% of prescribed units (CNAMTS, 2002).

Finally, the definition of the positive lists still remains a 'hot topic' for those people at the health and social security ministries who were interviewed for this study. The current French health policy combines the harmonisation of regulation with the reduction of health inequalities on the basis of a better knowledge of public health needs. However, this policy is being implemented in a context of increasing health expenditure, and especially of increasing user charges. It is a contradictory situation in which what is received from one hand is taken away by the other.

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### **NGAP procedures requiring prior authorisation**

Art. R 165-23 CSS : The registration order can make the reimbursement of certain products and services dependent on the prior accord of the reimbursement organisation, which is given after the obtaining of the opinion of the medical examiner. The agreement of the organisation is taken as given if no reply is received from it within the 15 days following the receipt of the request for prior authorisation.

Procedures requiring prior approval:

1. Procedures affecting the tissues in general, e.g. electrical epilation – 8 ; destruction of a post-traumatic tattoo – 20;
2. Cancerology – infusion of antimitotic substances – from 15 to 30;
3. Orthoptics – rehabilitation of decline in vision before the age of 18 years – 10, treatment of amblyopia, strabism – 5, and heterophoria -4;
4. Sinus – e.g. treatment of unilateral pansinusitis -120 KCC 50; treatment of facial palsy by musculocutaneous plasty repair – 80 KCC 30;
5. Dentofacial orthopaedics – e.g. treatment of dysmorphism – from 90 to 540; orthopaedic procedures for malformations resulting from total cleft lip or cleft palate – 200 (annual sum);
6. Preprosthetic surgery – muscle disinsertion – 40 KCC;
7. Larynx – individual rehabilitation – from 5 to 15;
8. Breast – implantation of a breast prosthesis (after mastectomy or mammary agenesis) – 60 KCC 30;
9. Electrocardiography – exercise training in patients with heart disease – 15;
10. Lipectomy extended to the abdominal wall for pendulous abdomen – 110 KCC 60;
11. Pedicure procedures – rehabilitation – 4; massage – 3;
12. Functional rehabilitation and readaptation – rehabilitation of sequelae of orthopaedic or rheumatologic disease – AMS from 7 to 9; rehabilitation of the abdominal wall – 7; rehabilitation of sequelae of respiratory tract disease – 7, vascular disease – 7; palliative care – 12;
13. Physical balneotherapy – 2.2;
14. Hyperbaric oxygen therapy, daily 1-hour sessions – 15;
15. Ultrasonographic surveillance of gravid foetal disease, biometrics and morphology – from 20 to 40, complementary examinations during third trimester of pregnancy – from 20 to 60;
16. Home surveillance and observation – beyond the first month, per visit – 1.

Medical appliances requiring prior approval (LPP: List of Professional Practices) :

1. Continuous pressure medical appliance for the treatment of sleep apnoea and associated practices;
2. Abdominal support orthoses (pathological wall) – prior approval limited to supplemental appliances other than waist support;
3. Custom-made elbow implant;
4. Knee implant – special total prosthesis – 4908.86 euros;
5. Custom-made osteosynthesis implants – 304.90;
6. Electrical wheel chair – from 2702.81 to 3939.01 euros;
7. Verticalising wheel chair – from 1559.84 to 5187.48;
8. Modular adjustable push chair – 962.20 euros;
9. Electrical device for verticalisation – 865.20 euros;
10. Adjustable chair for young children from the age of 18 months – 962.20 euros.

## **Legislation**

### **Les biens et services couverts par l'assurance maladie**

#### **Art. L. 321-1 CSS :**

*L'assurance maladie comporte :*

*1°) La couverture des frais de médecine générale et spéciale, des frais de soins et de prothèses dentaires, des frais pharmaceutiques et d'appareils, des frais d'analyses et d'examens de laboratoire, y compris la couverture des frais relatifs aux actes d'investigation individuels, des frais d'hospitalisation et de traitement dans des établissements de soins, de réadaptation fonctionnelle et de rééducation ou d'éducation professionnelle, ainsi que des frais d'interventions chirurgicales nécessaires pour l'assuré et les membres de sa famille, au sens fixé par l'article L. 313-3, y compris la couverture des médicaments, produits et objets contraceptifs et des frais d'analyses et d'examens de laboratoire ordonnés en vue de prescriptions contraceptives ;*

*2°) La couverture des frais de transport de l'assuré ou des ayants droit se trouvant dans l'obligation de se déplacer pour recevoir les soins ou subir les examens appropriés à leur état ainsi que pour se soumettre à un contrôle prescrit en application de la législation de sécurité sociale, selon les règles définies par les articles L. 162-4-1 et L. 322-5 et dans les conditions et limites tenant compte de l'état du malade et du coût du transport fixées par décret en Conseil d'Etat ;*

*3°) La couverture, sur décision de la commission d'éducation spéciale créée par l'article 6 de la loi n° 75-534 du 30 juin 1975, des frais d'hébergement et de traitement des enfants ou adolescents handicapés dans les établissements d'éducation spéciale et professionnelle, ainsi que celle des frais de traitement concourant à cette éducation dispensée en dehors de ces établissements, à l'exception de la partie de ces frais incombant à l'Etat en application de l'article 5 de la loi n° 75-534 du 30 juin 1975 ;*

*4°) La couverture des frais de soins et d'hospitalisation afférents à l'interruption volontaire de grossesse effectuée dans les conditions prévues à la section I du chapitre III bis du titre Ier du livre II du code de la santé publique ;*

*5°) L'octroi d'indemnités journalières à l'assuré qui se trouve dans l'incapacité physique constatée par le médecin traitant, selon les règles définies par l'article L. 162-4-1, de continuer ou de reprendre le travail ; l'incapacité peut être également constatée, dans les mêmes conditions, par la sage-femme dans la limite de sa compétence professionnelle et pour une durée fixée par décret ; toutefois, les arrêts de travail prescrits à l'occasion d'une cure thermale ne donnent pas lieu à indemnité journalière, sauf lorsque la situation de l'intéressé le justifie suivant des conditions fixées par décret.*

*6°) La couverture des frais relatifs aux actes et traitements à visée préventive réalisés dans le cadre des programmes mentionnés à l'article L. 1411-6 du code de la santé publique, et notamment des frais relatifs aux examens de dépistage et aux consultations de prévention effectués au titre des programmes prévus par l'article L. 1411-2 du même code ainsi que des frais afférents aux examens prescrits en application de l'article L. 2121-1 du même code et aux vaccinations dont la liste est fixée par arrêté des ministres chargés de la santé et de la sécurité sociale ;*

*7°) (Abrogé) ;*

*8°) (Abrogé) ;*

*9°) La couverture des frais relatifs à l'examen de prévention bucco-dentaire mentionné à l'article L. 2132-2-1 du code de la santé publique.*

### **Les listes positives d'actes médicaux et paramédicaux**

#### **Avant la Loi du 13 août 2004 :**

**Art L. 162-1-7** (Ordonnance n° 96-345 du 24 avril 1996 art. 16) *La prise en charge ou le remboursement par l'assurance maladie (Loi n° 99-1140 du 29 décembre 1999 art. 32) de « tout acte ou prestation » est subordonné à leur inscription sur une liste établie après avis de l'Agence Nationale d'Accréditation et d'Evaluation en santé mentionnée à l'article L. 1414-1 du code de la santé publique, dans les conditions fixées par décret en Conseil d'Etat.*

Ces dispositions sont d'application exclusive : les ministres compétents ne sauraient user des pouvoirs dont ils disposent, par ailleurs, pour arrêter les nomenclatures des actes professionnels et des actes de biologie pour fixer des conditions à la prise en charge de certains actes, soins et prestations, a fortiori pour restreindre les droits des assurés (CE 27 nov. 2000 : RSJ 2001, N)342).

#### Après la Loi du 13 août 2004 :

#### Art. L. 162-1-7 CSS

(Ordonnance n° 96-345 du 24 avril 1996 art. 16 Journal Officiel du 25 avril 1996, Loi n° 99-1140 du 29 décembre 1999 art. 32 I Journal Officiel du 30 décembre 1999, Loi n° 2003-1199 du 18 décembre 2003 art. 41 Journal Officiel du 19 décembre 2003 ; Loi n° 2004-810 du 13 août 2004 art. 42 Journal Officiel du 17 août 2004).

*La prise en charge ou le remboursement par l'assurance maladie de tout acte ou prestation réalisé par un professionnel de santé, dans le cadre d'un exercice libéral ou d'un exercice salarié en centre de santé ou dans un établissement ou un service médico-social, ainsi que, à compter du 1er janvier 2005, d'un exercice salarié dans un établissement de santé, à l'exception des prestations mentionnées à l'article L. 165-1, est subordonné à leur **inscription sur une liste établie** dans les conditions fixées au présent article. L'inscription sur la liste peut elle-même être subordonnée au respect d'indications thérapeutiques ou diagnostiques, à l'état du patient ainsi qu'à des conditions particulières de prescription, d'utilisation ou de réalisation de l'acte ou de la prestation.*

*La hiérarchisation des prestations et des actes est établie dans le respect des règles déterminées par des **commissions créées pour chacune des professions** dont les rapports avec les organismes d'assurance maladie sont régis par une convention mentionnée à l'article L. 162-14-1. Ces commissions, présidées par une personnalité désignée d'un commun accord par leurs membres, sont **composées de représentants des syndicats représentatifs des professionnels de santé et de représentants de l'Union nationale des caisses d'assurance maladie**. Un représentant de l'Etat assiste à leurs travaux.*

*Les **conditions** d'inscription d'un acte ou d'une prestation, leur **inscription** et leur **radiation** sont décidées par l'**Union nationale des caisses d'assurance maladie**, après avis de la Haute Autorité de santé et de l'Union nationale des organismes d'assurance maladie complémentaire.*

*Les décisions de l'Union nationale des caisses d'assurance maladie sont **réputées approuvées sauf opposition motivée des ministres chargés de la santé et de la sécurité sociale**. Le ministre chargé de la santé peut procéder d'office à l'inscription ou à la radiation d'un acte ou d'une prestation pour des raisons de santé publique par arrêté pris après avis de la Haute Autorité de santé. Dans ce cas, il fixe la hiérarchisation de l'acte ou de la prestation dans le respect des règles mentionnées ci-dessus. Les tarifs de ces actes et prestations sont publiés au Journal officiel de la République française.*

*Après avis de la Haute Autorité de santé, un acte en phase de recherche clinique ou d'évaluation du service qu'il rend peut être inscrit, pour une période déterminée, sur la liste visée au premier alinéa. L'inscription et la prise en charge sont soumises au respect d'une procédure et de conditions particulières définies par convention entre l'Union nationale des caisses d'assurance maladie et la Haute Autorité de santé.*

#### Article R162-52

(Décret n° 98-63 du 2 février 1998 art. 10 Journal Officiel du 5 février 1998 ; Décret n° 2001-532 du 20 juin 2001 art. 38 Journal Officiel du 22 juin 2001) ; Décret n° 2004-1368 du 16 décembre 2004 art. 1 Journal Officiel du 18 décembre 2004)

*I- Les tarifs fixés en application des conventions mentionnées à l'article L. 162-14-1 sont déterminés d'après une liste des actes et prestations établie dans les conditions prévues à l'article L. 162-1-7.*

*Cette liste peut comporter des majorations pour les actes accomplis dans des circonstances spéciales ou par certaines catégories de praticiens, en raison de leurs titres, de leur valeur scientifique, de leurs travaux ou de leur spécialisation. Elle détermine, en pareil cas, les conditions d'application de ces majorations.*

*La liste peut également comporter des prescriptions de nature à faciliter le contrôle médical de certains actes.*

*Lorsqu'un accord est exigé, en application du présent I, préalablement au remboursement d'un acte ou d'un traitement par un organisme de sécurité sociale, le silence gardé pendant plus de quinze jours par cet organisme sur la demande de prise en charge vaut décision d'acceptation.*

II. - Avant de procéder aux consultations rendues obligatoires par le troisième alinéa de l'article L. 162-1-7, l'Union nationale des caisses d'assurance maladie informe de son intention d'inscrire un acte ou une prestation, d'en modifier les conditions d'inscription ou de procéder à sa radiation les ministres chargés de la santé et de la sécurité sociale, l'Union nationale des professionnels de santé, les organisations représentatives des professionnels de santé autorisés à pratiquer l'acte ou la prestation et les organisations représentatives des établissements de santé.

Les avis de la Haute Autorité de santé et de l'Union nationale des organismes d'assurance maladie complémentaire sont rendus au plus tard à la fin du sixième mois qui suit la date à laquelle elles sont saisies par l'Union nationale des caisses d'assurance maladie. A titre exceptionnel, lorsque des travaux supplémentaires sont nécessaires, la Haute Autorité de santé peut rajouter à ce délai un délai supplémentaire qui ne peut excéder six mois. Passé ces délais, les avis sont réputés rendus,

Lorsque, pour l'application des dispositions de l'article L. 161-29, la liste est modifiée pour être établie par référence à un numéro de code de l'acte ou de la prestation, les deux avis mentionnés ci-dessus sont requis si l'acte ou la prestation ne figurait pas sur la liste antérieure et peuvent être sollicités au cas contraire par l'Union nationale des caisses d'assurance maladie mentionnée à l'article L. 182-2.

Ces avis sont adressés aux ministres chargés de la santé et de la sécurité sociale, à l'Union nationale des caisses d'assurance maladie, ainsi qu'aux autres personnes morales mentionnées au premier alinéa du présent II.

III. - La décision d'inscription d'un acte ou d'une prestation mentionne les indications thérapeutiques ou diagnostiques tenant compte notamment de l'état du patient ainsi que les conditions particulières de prescription, d'utilisation ou de réalisation de l'acte ou de la prestation.

L'Union nationale des caisses d'assurance maladie définit le tarif de l'acte ou de la prestation dans le respect des règles de hiérarchisation établies par les commissions mentionnées à l'article L. 162-1-7. Lorsque l'acte ou la prestation constitue une alternative à des traitements thérapeutiques déjà inscrits sur la liste mentionnée à l'article L. 162-1-7, l'Union nationale des caisses d'assurance maladie évalue l'opportunité de l'inscription de l'acte ou de la prestation et définit, le cas échéant, son tarif au regard des coûts de mise en oeuvre comparés de ces différents traitements.

**La décision de l'Union nationale des caisses d'assurance maladie sur les conditions d'inscription d'un acte ou d'une prestation, leur inscription ou leur radiation, accompagnée des avis mentionnés au II ci-dessus et d'une estimation chiffrée de son impact financier, est transmise aux ministres chargés de la santé et de la sécurité sociale.**

Les ministres compétents peuvent s'opposer à la décision de l'Union nationale des caisses d'assurance maladie dans un délai de quarante-cinq jours. Passé ce délai, la décision est réputée approuvée.

L'opposition des ministres compétents est motivée et notifiée à l'Union nationale des caisses d'assurance maladie. Les ministres en informent la Haute Autorité de santé et l'Union nationale des organismes d'assurance maladie complémentaire, ainsi que les autres personnes morales mentionnées au premier alinéa du II ci-dessus.

IV. - En cas d'inscription et de prise en charge d'un acte en phase de recherche clinique ou d'évaluation du service qu'il rend, la convention mentionnée au dernier alinéa de l'article L. 162-1-7, accompagnée de l'avis de la Haute Autorité de santé, est adressée au ministre chargé de la santé et au ministre chargé de la sécurité sociale qui statuent dans les conditions et délai mentionnés à l'article L. 162-15.

## **Conditions de prise en charge pour les médicaments**

### **Après la loi du 13 août 2004**

**Art. L. 162-17 CSS** (Ordonnance n° 96-345 du 24 avril 1996 art. 22 I Journal Officiel du 25 avril 1996 ; Loi n° 99-1140 du 29 décembre 1999 art. 32 VII Journal Officiel du 30 décembre 1999 ; Loi n° 2001-1246 du 21 décembre 2001 art. 40 I Journal Officiel du 26 décembre 2001 ; (Loi n° 2004-806 du 9 août 2004 art. 128 I Journal Officiel du 11 août 2004 ; Loi n° 2004-810 du 13 août 2004 art. 31 IV Journal Officiel du 17 août 2004).

Les médicaments spécialisés, mentionnés à l'article L. 601 du code de la santé publique et les médicaments bénéficiant d'une autorisation d'importation parallèle mentionnée à l'article L. 5124-17-1 du même code, ne peuvent être pris en charge ou donner lieu à remboursement par les caisses d'assurance maladie, lorsqu'ils sont dispensés en officine, que s'ils figurent sur une liste établie dans les conditions fixées par décret en Conseil d'Etat. La liste précise les seules indications thérapeutiques ouvrant droit à la prise en charge ou au remboursement des médicaments.

*Les médicaments inscrits sur la liste prévue à l'article L. 5126-4 du code de la santé publique sont pris en charge ou donnent lieu à remboursement par l'assurance maladie lorsqu'ils sont délivrés par une pharmacie à usage intérieur d'un établissement de santé dûment autorisée. Cette liste précise les seules indications thérapeutiques ouvrant droit à la prise en charge ou au remboursement des médicaments.*

*L'inscription d'un médicament sur les listes mentionnées aux premier et deuxième alinéas peut, au vu des exigences de qualité et de sécurité des soins mettant en oeuvre ce médicament, énoncées le cas échéant par la commission prévue à l'article L. 5123-3 du code de la santé publique, être assortie de conditions concernant la qualification ou la compétence des prescripteurs, l'environnement technique ou l'organisation de ces soins et d'un dispositif de suivi des patients traités*

*En ce qui concerne les médicaments officinaux et les préparations magistrales, un décret en Conseil d'Etat détermine les règles selon lesquelles certaines catégories de ces médicaments peuvent être exclues du remboursement par arrêté interministériel.*

#### **Avant la Loi du 13 août 2004 :**

**Art. L. 162-17 du Code de la Sécurité sociale** *Les médicaments spécialisés, mentionnés à l'article L. 5121-8 du code de la santé publique, ne peuvent être pris en charge ou donner lieu à remboursement par les caisses d'assurance maladie (L. n° 2001-1246 du 21 déc. 2001, art. 40-I), « lorsqu'ils sont dispensés en officine », que s'ils figurent sur une liste établie dans les conditions fixées par décret en Conseil d'Etat (Ordonnance n° 96-345 du 24 avril 1996 art. 22 I). La liste précise les seules indications thérapeutiques ouvrant droit à la prise en charge ou au remboursement des médicaments.*

*(Loi n° 2001-1246 du 21 décembre 2001 art. 40) Les médicaments inscrits sur la liste prévue à l'article L. 5126-4 du code de la santé publique sont pris en charge ou donnent lieu à remboursement par l'assurance maladie lorsqu'ils sont délivrés par une pharmacie à usage intérieur d'un établissement de santé dûment autorisée. Cette liste précise les seules indications thérapeutiques ouvrant droit à la prise en charge ou au remboursement des médicaments.*

*En ce qui concerne les médicaments officinaux et les préparations magistrales, un décret en Conseil d'Etat détermine les règles selon lesquelles certaines catégories de ces médicaments peuvent être exclues du remboursement par arrêté interministériel V. art. R.. 162-19.*

1. Les mesures d'inscription d'une spécialité sur la liste des médicaments et spécialités remboursables revêtent un caractère réglementaire.

2. Les mesures d'inscription d'une spécialité sur la liste des médicaments et spécialités remboursables ressortissent au champ d'application de la directive n°89/105/CEE du 21 déc. 1988 régissant la fixation des prix des médicaments à usage humain et leur inclusion dans le champ d'application des systèmes nationaux d'assurance maladie

3. Le juge de l'excès de pouvoir exerce un contrôle minimum sur les mesures d'inscription sur la liste des médicaments et spécialités remboursables.

#### **Conditions de prise en charge pour les dispositifs médicaux**

##### **Art. L. 165-1 CSS :**

*Le remboursement par l'assurance maladie des dispositifs médicaux à usage individuel, des tissus et cellules issus du corps humain quel qu'en soit le degré de transformation et de leurs dérivés, des produits de santé autres que les médicaments visés à l'article L. 162-17 et des prestations de services et d'adaptation associées est subordonné à leur inscription sur une liste établie après avis d'une commission de la Haute Autorité de santé mentionnée à l'article L. 161-37. L'inscription est effectuée soit par la description générique de tout ou partie du produit concerné, soit sous forme de marque ou de nom commercial. L'inscription sur la liste peut elle-même être subordonnée au respect de spécifications techniques, d'indications thérapeutiques ou diagnostiques et de conditions particulières de prescription et d'utilisation.*

*Les conditions d'application du présent article, notamment les conditions d'inscription sur la liste, ainsi que la composition et le fonctionnement de la commission sont fixées par décret en Conseil d'Etat.*

*La procédure et les conditions d'inscription peuvent être adaptées en fonction des dispositifs selon leur finalité et leur mode d'utilisation.*

Lorsque l'utilisation de produits ou prestations fait appel à des soins pratiqués par des établissements de santé, les ministres chargés de la santé et de la sécurité sociale peuvent décider de subordonner l'inscription sur la liste des conditions relatives à l'évaluation de ces produits ou prestations aux modalités de délivrance des soins ou à la qualification ou à la compétence des praticiens des établissements de santé utilisant ces produits ou pratiquant ces prestations. La liste précise, le cas échéant, les modalités selon lesquelles le directeur de l'agence régionale de l'hospitalisation établit la liste des établissements de santé pour lesquels l'assurance maladie prend en charge ces produits ou prestations, au vu notamment des capacités hospitalières nécessaires pour répondre aux besoins de la population, ainsi que de l'implantation et de l'expérience pour les soins concernés des établissements de santé.

## **La participation de l'assuré**

### Avant la loi d'août 2004

**La participation de l'assuré aux tarifs servant de base au calcul des prestations prévues aux 1°, 2° et 3° de l'article L. 321-1 est fixée par un décret en Conseil d'Etat.**

Elle peut être proportionnelle aux dits tarifs ou être fixée à une somme forfaitaire. Elle peut varier selon les catégories de prestations, les conditions dans lesquelles sont dispensés les soins, les conditions d'hébergement, la nature de l'établissement où les soins sont donnés. La participation de l'assuré peut être réduite en fonction de l'âge ou de la situation de famille du bénéficiaire des prestations.

### Après la loi d'août 2004

**Art. L. 322-2 CSS** (Loi n° 2004-810 du 13 août 2004 art. 20 I, art. 41 I Journal Officiel du 17 août 2004) :

**I. - La participation de l'assuré aux tarifs servant de base au calcul des prestations prévues aux 1°, 2° et 3° de l'article L. 321-1 peut être proportionnelle aux dits tarifs ou être fixée à une somme forfaitaire.** Elle peut varier selon les catégories de prestations, les conditions dans lesquelles sont dispensés les soins, les conditions d'hébergement, la nature de l'établissement où les soins sont donnés. La participation de l'assuré peut être réduite en fonction de l'âge ou de la situation de famille du bénéficiaire des prestations.

La participation **est fixée** et peut être, dans les cas mentionnés à l'article L. 322-3, **réduite ou supprimée**, dans des limites et des conditions fixées par **décret en Conseil d'Etat, par décision de l'Union nationale des caisses d'assurance maladie, après avis de l'Union nationale des organismes d'assurance maladie complémentaire.** Le ministre chargé de la santé peut s'opposer à cette décision pour des motifs de santé publique. La décision du ministre est motivée.

L'application aux spécialités pharmaceutiques mentionnées à l'article L. 162-17 des taux de participation mentionnés à l'alinéa précédent est déterminée par décision de l'Union nationale des caisses d'assurance maladie.

**II. - L'assuré acquitte une participation forfaitaire pour chaque acte ou pour chaque consultation pris en charge par l'assurance maladie et réalisé par un médecin, en ville, dans un établissement ou un centre de santé, à l'exclusion des actes ou consultations réalisés au cours d'une hospitalisation. L'assuré acquitte également cette participation pour tout acte de biologie médicale. Cette participation se cumule avec celle mentionnée au I. Son montant est fixé, dans des limites et conditions prévues par décret en Conseil d'Etat, par l'Union nationale des caisses d'assurance maladie conformément à la procédure fixée au I.**

Un décret fixe le nombre maximum de participations forfaitaires supportées par chaque bénéficiaire au titre d'une année civile.

Lorsque plusieurs actes ou consultations sont effectués par un même professionnel de santé au cours d'une même journée, le nombre de participations forfaitaires supportées par le bénéficiaire ne peut être supérieur à un maximum fixé par décret.

Un décret fixe les conditions dans lesquelles, lorsque l'assuré bénéficie de la dispense d'avance des frais, la participation forfaitaire peut être versée directement par l'assuré à la caisse d'assurance maladie ou être récupérée par elle auprès de l'assuré sur les prestations à venir. Il peut être dérogé aux dispositions de l'article L. 133-3.

Nota : Loi 2004-810 2004-08-13 art. 20 V : jusqu'à l'intervention de la décision de l'Union nationale des caisses d'assurance maladie prévue au II de l'art. L322-2, dans sa présente rédaction, le montant de la participation mentionnée audit II est fixé par décret.

## **Conditions d'exonération du ticket modérateur**

### **Art. L. 322-3 CSS :**

1°) lorsque, à l'occasion d'une hospitalisation ou au cours d'une période de temps déterminée, la dépense demeurant à la charge de l'intéressé dépasse un certain montant ;

2°) lorsque l'état du bénéficiaire justifie la fourniture d'un appareil appartenant à une catégorie déterminée par ledit décret, pour les frais d'acquisition de l'appareil ;

3°) lorsque le bénéficiaire a été reconnu atteint d'une des affections, comportant un traitement prolongé et une thérapeutique particulièrement coûteuse, inscrites sur une liste établie par décret après avis de la Haute Autorité mentionnée à l'article L. 161-37 ;

4°) lorsque le bénéficiaire a été reconnu par le contrôle médical atteint d'une affection non inscrite sur la liste mentionnée ci-dessus, et comportant un traitement prolongé et une thérapeutique particulièrement coûteuse ;

5°) lorsque l'assuré est titulaire de l'allocation supplémentaire du fonds national de solidarité au titre d'un avantage vieillesse ;

6°) lorsque le bénéficiaire est un enfant ou adolescent handicapé pour les frais couverts au titre du 3° de l'article L. 321-1 ;

7°) lorsque l'assuré est hébergé dans un établissement mentionné à l'article 3 de la loi n° 75-535 du 30 juin 1975 ou lorsqu'il bénéficie de soins dispensés par un centre mentionné à l'article L. 355-1-1 du code de la santé publique ;

8°) lorsque l'assuré est hébergé dans une unité ou un centre de long séjour mentionné à l'article L. 174-5 ou à l'article 52.1 de la loi n° 70-1318 du 31 décembre 1970 ;

9°) lorsque l'assuré bénéficie de soins paramédicaux dispensés dans le cadre d'une action médico-sociale de maintien à domicile par les institutions mentionnées au 1° de l'article 1er de la loi n° 75-535 du 30 juin 1975 ;

10°) Abrogé.

11°) Pour l'hospitalisation des nouveau-nés lorsqu'elle se produit pendant une période fixée par décret en Conseil d'Etat, ainsi que pour tous les soins qui leur sont dispensés en établissement de santé, jusqu'à un âge fixé par décret en Conseil d'Etat ;

12°) pour les investigations nécessaires au diagnostic de la stérilité et pour le traitement de celle-ci, y compris au moyen de l'insémination artificielle ;

13°) pour les bénéficiaires des dispositions des articles L. 311-10, L. 313-4, L. 341-16 et L. 371-1 en ce qui concerne les frais engagés pour eux-mêmes ;

14°) pour les ayants droit des bénéficiaires des dispositions de l'article L. 371-1 ;

15°) pour les soins consécutifs aux sévices subis par les mineurs victimes d'actes prévus et réprimés par les articles 222-23 à 222-32 et 227-22 à 227-27 du code pénal ;

16°) Pour les frais d'examens de dépistage et les frais liés aux consultations de prévention destinées aux mineurs effectués dans le cadre des programmes mentionnés au 6° de l'article L. 321-1 ;

17°) Pour les frais relatifs à l'examen de prévention bucco-dentaire mentionné au 9° de l'article L. 321-1. La liste mentionnée au 3° du présent article comporte également en annexe les critères médicaux utilisés pour la définition de l'affection et ouvrant droit à la limitation ou à la suppression de la participation de l'assuré.

Sur proposition de l'Union nationale des caisses d'assurance maladie, un décret, pris après avis de la haute autorité mentionnée à l'article L. 161-37, peut réserver la limitation ou la suppression de la participation des assurés en application des 3° et 4° du présent article aux prestations exécutées dans le cadre d'un réseau de santé ou d'un dispositif coordonné de soins.