

HEALTH SERVICE BENEFIT CATALOGUES IN EUROPE

COUNTRY REPORT: ITALY

Health/BASKET Project

SP21-CT-2004-501588

*Giovanni Fattore
Aleksandra Torbica*

Bocconi University

1. OVERVIEW

The issue of the definition of a health benefit basket in Italy is deeply embedded in the history of Italian National Health Service (INHS) and its reforms over the past three decades. The definition of the benefit package has been much debated within Italy's health care system. Benefit basket, intended as the overall set of services guaranteed to citizens under public coverage across the national territory, has changed throughout the years in its form, contents and objectives.

The Italian Constitution of 1948 expressly provides for a right for health. This constitutional guarantee is expressed in very general terms. Article 32 of the Constitution says that "Republic protects health as a fundamental right of the individual and as a concern of collectivity and guarantees free care to the indigent". In other words, according to the Constitution all Italian citizens have a right to health, but only poor ones have the right to free care. Furthermore, it implicitly says that the right to health without the means to finance health care would be an empty right. Consequently, the definition of standard benefit package in the INHS has evolved hand in hand with the development of the health care system and, particularly, of its funding arrangements.

The principle of a package of benefits available to all citizens irrespective of age, social condition or income was introduced with the 1978 reform, which founded the INHS (Law n.833/1978). Article 1 of Law 833 reproduces article 32 of the Constitution almost to the letter: "the Republic protects health as a fundamental right of the individual and concern of collectivity by means of the NHS". The expression "levels of care " was mentioned for the first time with the objective to guarantee equal health care coverage across national territory: "the State was to set objectives for eliminating geographical differences in social and health care conditions" (art.2) and "and to determine *levels of care* to be guaranteed to all citizens" (art.3). Law 833 (article 19) also introduces one of the essential characteristics of INHS according to which patients have the right to choose "provider and place of treatment".

Although the reform listed the areas in which treatments were to be delivered directly by the NHS, it did not define the benefits to be included and excluded in detail, leaving such responsibility to the National Health Plan, a 3-year document that was intended to guide action at regional and local level and to lay out the main guidelines for the provision of health care services.

However, the National Health Plan was not officially released in the '80s. The prevailing philosophy in that period was that all services which were technologically possible and useful should be provided to NHS patients. In the absence of an explicit definition of services to be guaranteed, several court sentences affirmed that patients have the right to full and complete protection since "the right to health is primary and fundamental", regardless of financial sustainability of providing those services.

The funding system was completely centralised: resources were collected at central level, pooled in a National Health Funds and allocated to regions according to a mix of need and historical spending criteria. This solution was deemed appropriate to promote geographical equity in the system. However, regions and health care organizations systematically overrun their budget, claiming the resources made available by the State were not sufficient to provide a comprehensive protection to citizens. In order to impose keep expenditure under control, the central government tried to make regions accountable for responsible for financial deficits. However, the regions successfully appealed to the Constitutional Court against such a strategy, arguing that it was the central government to decide what services should and shouldn't be provided. It is interesting to notice, that without the definition of the basic package guaranteed to citizens, it was not possible to keep regions financially

accountable. Without such a package, regions and healthcare organisation running deficits could always claim that this was necessary to meet the “primary and fundamental right to health”

Despite the efforts of successive governments, the first National Health Plan was approved in 1994, 16 years after the NHS was established. Once again, the National Health Plan did not specify the benefits to be provided by the local health units but simply defined six categories of interventions, ranging from hospital care to prevention and from specialist care to primary care:

1. public and occupational health care services
2. basic (primary) health care services
3. specialist semiresidential and community care
4. hospital care
5. residential (long-term) health care to non self-sufficient categories
6. support activities for organization and management of health care delivery

In the beginning of the 1990s, the courts began to recognize that the INHS might have to be selective in the kind of care it provides. Various sentences reflected the conviction that INHS can not provide all care which is available; this new attitude empowered the Ministry of Health and the regions to take action on the definition of which services are clinically valid and necessary.

A major reform of the health sector was passed in 1992/1993 (Decreets 502/92 and 517/93); it entailed three major changes that re-shaped the public healthcare system: devolution of powers to regions, managerialism and competition in health service provision. The new legislation entitled regions to receive funding from the central government in accordance with its residence population (*quota capitaria*). The national government defined the set of services to be provided under NHS coverage (*uniform levels of care* (LUAs-livelli uniformi di assistenza)). Regions are hold accountable for providing those services and are financially responsible for the additional expenditure incurred with respect to the level determined necessary for provision of uniform levels of care. They can also exceed the uniform levels of care provided that they use their own resources.

However, the reform designed a new logical framework but did not define the content of the uniform levels of care. During the '90s the principle that the NHS can only offer a specified set of guarantees was clearly legislated and gained acceptance, but to make operational the LUAs concept appeared a very difficult task. LUAs were not specified and it remained unclear what the NHS was mandated to provide.

In practice, the *quota capitaria* seemed to be determined by simply dividing the annual amount of funding available to Ministry of Health (assigned by Ministry of the Treasury) to the regions on the basis of the resident population. Consequently, the *uniform levels of care* were perceived as a tool aimed at concealing the intention of the government to set up upper limit on the central transfers.

Throughout the 1990s, Italian health jurisprudence addressed the question of access by patients to specific services in numerous occasions. The main criteria to which the majority of courts explicitly referred to was that of clinical effectiveness: several court decisions declared legitimate the refusal of local health authorities to provide certain services on the grounds that the treatment was not of proven clinical effectiveness. In some occasions regional courts have argued that the fact that a medical service has not been approved by national health authorities doesn't necessarily mean that it should be withheld from patients. The courts stated that what counts in deciding when to allow free provision of a service is not depending on proven clinical effectiveness but on whether the service is indispensable (necessary) to improve patients' health and cannot be substituted. Consequently, the set of services to which the citizens were entitled varied extensively among the regions. The definition of national standards was further urged.

Significant progress was made in the late '90s with the approval of the National Health Plan (NHP) 1998-2000. The Plan stressed the need for an explicit definition of the content of the benefit package that should be met by all regions. In addition, it laid out the general guidelines as well as the initial steps required to define the benefit package. The last part of the NHP detailed the process that the national government intended to follow to specify the extent of NHS coverage. The document clarified 4 major steps in defining uniform levels of care. 1) definition of principles; 2) precise definition of principles to be guaranteed and appropriateness criteria for their use; 3) determination of the level of per-capita funding required to provide guaranteed services and 4) definition of a set of tools to monitor the implementation of uniform levels of care across Regions.

The first step concerns the explicit statement of the general principles underlying the specification of the services to be guaranteed by the NHS. In the second step, the main areas of NHS coverage are defined. For each main area, the set of services to be guaranteed to all citizens throughout the national territory, regardless of their residence or income level, have to be specified in the third step. The specific definition of these services is coupled with the identification of appropriateness criteria. The fourth step entails a financial analysis to estimate the amount of resources required to provide the set of services defined; the aim of this stage is to define the level of per capita funding to make available to all regions. The main feature of this reform was the linkage between levels of care and financial resources. The estimate of per-capita funding should have been used as a basis to estimate total NHS expenditure; i.e. national funding should have been calculated starting from the forecasted financial requirements to ensure that the guaranteed set of services can be provided to the entire Italian population. The final step concerned the design of an operation system to monitor the implementation of the entitlements at regional and local level.

With regard to the first step, the NHP 1998-2000 stated numerous principles: human dignity, health protection, need, solidarity, efficacy and appropriateness, efficiency in service provision, equity in the access of care. The list appears long and does not suggest a clear direction for the definition of operational criteria. In 1999, new legislation reforming the Italian NHS (decree 229/99) restricted the criteria to four: 1) human dignity; 2) effectiveness; 3) appropriateness and 4) efficiency.

The 1999 reform strongly underlined the importance of the principle of equity in the access of care and introduced a new expression "essential levels of care" (LEA-Livelli Essenziali di Assistenza). The concept of LEA represents one of the mostly debated policy tools implemented by Italian NHS in recent decades. At the moment of their inception, LEAs were perceived as a key policy tool aimed at regulating the relations between the State and the Regions (mainly financial) and ensuring the territorial equity within national borders.

However, disillusion with LUAs/LEAs was mounting as in almost ten years no progress had made to make the concept operational. Substantial progress in the definitions of LEAs was necessary to give credibility to the concept and to the overall strategy of re-distribution of powers between the state and the regions. This progress was made with the agreement between the Regions and the State reached on August 8th 2001 (at the Permanent Conference between the State and Regions) which was followed by a Governmental decree (Dpcm) on November 29th 2001 to make the agreement a national law.. At present, this decree is the pivotal element of the Italian health benefit catalogue.

Through this document the central government exercised its right to set essential levels of care. According to a recent Constitutional Reform (Constitutional Law n.3, October 18th 2001), powers on how to organise, fund and manage health services are matters of concurrent legislation between the State and the regions. However, the State maintains the right to set essential levels of those services representing civil and social rights to be guaranteed within national borders.

In short, according to the present Italian Constitutional Law the entitlements ought to be defined by the central government (not by Regions) while the legislative power on health protection (but not on standards) is shared by the central and regional governments.

The State-Regions agreement, followed by the Governmental decree confirmed the link between the definition of services to be provided and the resources available, introduced in the 1992 legislation. An important difference, however, is that in the current legislation funding is determined concurrently and in line with services identified and not ex-ante as in the past. It was debated that , the underlying logic in defining entitlements passed from the one according to which all Italians have the right to the same “per-capita expenditure” , to the one stating that all Italians are entitled to the same “services”.

Governmental decree “Definition of essential levels of care” (DPCM, November 29th 2001) represents the first step in this direction. As already mentioned, the document was elaborated and prepared by the Ministry of Health in collaboration with the Regions. Overall, the decree defines the main areas of healthcare services to be guaranteed by the NHS (positive list) , those completely excluded by NHS coverage (negative list) and those partially covered (only available for specific clinical conditions).

In facts, the positive list represents the recognition and systematisation of the current legislation (other decrees, laws, guidelines, ecc), i.e. it includes all the services that NHS is actually providing categorized in three macro-levels of care: 1) public health services; 2) community care; 3) hospital care.

The list of services to be guaranteed by NHS is unique for all 21 Italian Regions and the State is mandated to ensure adequate funding for making the services available. The Regions may autonomously decide whether to provide some additional services to their citizens from their own resources.

The agreement between the State and the Regions mentioned above defined also a system to monitor LEA implementation across the country. This responsibility has been assigned to a special technical body established in April 2002 and made of representatives of central (Ministry of Health, Ministry of Economy and Finance) and regional governments- the Monitoring Committee. The main objective of the commission is to “monitor and verify the actual provision of services included in the LEAs and their costs in respect to the resources estimated and assigned”. It is not clear whether this supervision of LEAs implementation is coupled by some kind of sanction mechanism that would allow central government to intervene in case the regions do not comply with LEAs provision. The Constitutional Law approved in 2001 allows the central government to “replace regions in the case of their inactivity with regard to essential levels concerning basic civil and social rights” (art.120). Until present, however, the central government has not defined explicitly the criteria according to which it would be possible to assess that a particular region doesn’t respect LEAs.

Only recently a new technical body has been established (Ministry decree on February 25th 2004)- the National LEA Commission whose main objective is that of up-dating the national health basket on the basis of scientific, technological and economic evidence. The Commission is set up of 14 members: 6 experts of healthcare management, planning and organizational sciences are nominated by Ministry of health; 7 are regional representatives and 1 is from the Ministry of Economy and Finance.

In conclusion, the role of the central government is that of ensuring adequate funding, supervising and monitoring the provision of healthcare services included in LEAs. The government (Ministry of Health) provide a national guarantee to citizens that their rights are protected regardless of where they live in the country.

The role of the central government is also to periodically up-date services included in the benefit basket on the basis of population health indicators, health care demand and the availability of new technologies.

The Regions, responsible for localisation and organisation of healthcare facilities, are held accountable for the provision of healthcare services included in the benefit package. Central funding is expected to cover the provision of those services. In case the funding is not sufficient, regions are obliged to add their own resources in order to guarantee the provision. On the other hand, regions are allowed to use resources freed by efficiency gains. More specifically, the regions are responsible for ensuring the appropriate provision of LEAs in order to guarantee the rational use of resources at different levels of care (in-patient, day hospital and day surgery, out-patient). Finally, regions may implement additional services from their own financial resources.

The first results of the Monitoring Committee showed that all Italian regions are far from implementing LEAs in a restrictive manner or attempting to reduce the services to be guaranteed. On the contrary, regions have been generally moving in the opposite direction and have invested in the provision of services beyond those guaranteed by central level, in various sectors. This resulted in different sets of services made available under public coverage, and therefore different benefit packages between regions. However, the differences mainly regard few specific sectors such as alternative medicine, outpatient physiotherapy, rehabilitation services and dental care.

The importance of LEAs is further underlined in the last National Health Plan (2003-2005). "*To implement, monitor and regularly up-date essential and appropriate levels of care*" is set as one of the goals of national health policy in the three-year period. The plan lists the following fundamental principles to be considered in this process:

- services provided, in order to be guaranteed, must be measurable with adequate indicators
- services that are included in the benefit packages may not be considered essential if not appropriately delivered
- appropriateness of services is linked to their correct utilization and not to specific service type
- indicators are set at different levels of care (community, hospital, working places) in order to verify the appropriate resource utilization

To summarise, the content of the Italian health basket and the criteria upon which is designed have changed several times. Changes have been mainly driven by the two sets of policy objectives: (i) ensuring equity in services available across national territory and (ii) controlling NHS expenditure.

At present, the Italian health basket (LEAs) is perceived as a fundamental policy tool in order to pursue those goals.

Services excluded from the benefit basket

The Governmental decree provides a list of services for which public funding may not be guaranteed and clearly states the reason behind this decision: "services whose efficacy is not scientifically proven, which do not meet efficiency criteria and which do not satisfy primary needs" .

Services explicitly excluded from the NHS coverage are the following:

- a) Plastic surgery not following accidents, diseases or genetic malformations;
- b) ritual male circumcision;
- c) non conventional medicine (acupuncture, phyto-therapy, ayurvedic medicine, homeopathy, chiropractic care, osteopathy and all other non conventional care not specified);
- d) non obligatory vaccinations for travelling purposes;
- e) medical certifications (except for scholars);
- f) some outpatient rehabilitation and physiotherapy services (assisted exercises in water; hydromassotherapy, short-wave diathermy, acupuncture, hypothermia NAS, massotherapy, pressotherapy, analgic electrotherapy, ultrasound therapy, iontophoreses, laser analgic therapy, therapeutic photophoreses, extracorporeal photo-chemo therapy). Regions are autonomous in deciding whether to include analgic laser and electro therapy, ultrasound therapy among services available for specific clinical conditions.

In addition, the following categories of services are only partially covered by NHS; their provision is limited to special patient categories with specific clinical conditions:

- a) dental care
- b) bone densitometry (available for conditions for which there is proven clinical efficacy)
- c) some physical therapy and rehabilitation services in outpatient setting
- d) refractory laser surgery (available for patients who cannot wear glasses or lenses)

As to services completely and/or partially excluded, regions are free to decide whether to include them in their regional set of services available to citizens. The provision of these services, in that case, must be guaranteed from regional resources. Thus, due to interregional variability, it is pretty difficult to define which types of service categories are actually excluded from the benefit basket in Italian NHS.

In the following sections, the measures introduced by various regions will be explained in more detail.

Table 1. Benefit-defining laws/ decrees and catalogues

	DPCM November 29 th 2001: "Definition of Essential Levels of Care"	DM July 22 nd 1996: "Specialist outpatient services"	National Pharmaceutical Formulary	Guidelines on Rehabilitative Care adopted on May 7 th 1998	DM 332/1999: "Prosthetic appliances: tariffs and provision modalities"	National Contract for Primary care
In-patient curative care	X					
Day-cases of curative care	X					
Primary care	X					X
Out-patient dental care	X					
Specialist out-patient care	X	X				
Alternative medicine	X					
Rehabilitative care	X			X		
-inpatient	X			X		
-day cases	X			X		
-out-patient	X	X		X		
-home care	X			X		
Long-term nursing care	X					
Clinical laboratory		X				
Diagnostic Imaging		X				

Emergency rescue	X					
Pharmaceuticals	X		X			
Therapeutical appliances	X				X	
Prevention and public health services	X					
Legal status: law, decree ...	Legislative decree	Ministry Decree	Agency administrative act	Law	Legislative decree	Presidential decree
Decision-maker	Permanent State-Regions Conference Ministry of Health	Ministry of Health	National Drug Agency	Ministry of health	Ministry of Health	Ministry of health; Trade-Unions of Primary physicians
(original) purpose, e.g. entitlements, reimbursement, target-setting	Entitlements	Fee-schedule	Positive list	Guidelines	Fee-schedule	Entitlements
Positive/ negative definition of benefits	P and N	P	P	P	P	P
Degree of explicitness: 1 "all necessary"/ 2 areas of care/ 3 items	2	3	3	1	3	1 / 2
If itemised: goods/ procedures only; linked to indications		Procedures, sometimes linked to indications	Goods, for certain categories specific indications (Prescription Notes)		Goods	
Updating	Foreseen	No at national level Regular at regional level	Regularly (annually)	No	No	Yes, every 2-3 years
* need	X				X	X
* costs	X	X	X		X	
* effectiveness		X	X			X
* cost-effectiveness						
* budget	X					X
* appropriateness	X			X		X

2. DEFINITIONS OF ENTITLEMENTS AND BENEFITS BY SECTOR

In the Italian NHS, there is a common decision making process for most of the functional categories defined by the OECD. More specifically, most of the services included in the benefit basket are determined at central level upon agreement between the State and the Regions (Permanent Conference on State-Regions relations) (Figure 1). The composition and characteristics of this decision body will be described in detail in section three of the present report.

The most important exception to this decision making framework is represented by pharmaceuticals (Figure 2).

Services of curative care

In-patient curative care

Traditionally, services to be provided in hospital settings have never been explicitly defined in the Italian NHS: it has been rather implicitly recognized that all types of services deemed to be *appropriately* delivered at hospital level gave to be available to citizens. Governmental decree (Dpcm November 29th 2001) defines 7 chapters as broad categories of services to be delivered in the hospital:

- 1) emergency services
- 2) ordinary admissions (inclusive of rehabilitative and long-term in-patient care)
- 3) day hospital care
- 4) day surgery
- 5) curative home-care
- 6) collection, diffusion, control of blood-components and transfusion services
- 7) organ and tissue transplantation services

Furthermore, it is explicitly recognised that some benefits that are not available in other settings like non reimbursable pharmaceuticals (class C) or diagnostic tests not included in the positive list of out-patient services (see section 3 for more detail) are provided under public coverage if delivered during hospital stay.

For only few categories of those listed above further indications are available with regards to what services are provided within the specific category.

A possible list of the services provided in Italian hospitals may be derived by the current financing system. In 1995, the hospital financing reform introduced a DRG-based system for inpatient care. DRG tariffs refer to both ordinary acute hospital admissions and day hospital treatments. In addition to this per case type of payment, per-diem reimbursements still apply for rehabilitation and long-term care (for rehabilitation services the amount varies among different Major Diagnostic Categories). A progressive rate reduction scheme is applied in order to prevent long unnecessary hospital stay.

The DRG list was originally set at central level while the Regions were given the autonomy to define the tariffs according to the local production costs of services (Legislative Decree of December 14th 1994; last update on June 30th 1997). Regions are free to redefine the rates according to their own standards but must take the national rates as the maximum level.

The characteristics of the DRG-based funding mechanism varies extensively among regions. Many regions have developed their own fee schedules while others apply national tariffs. Also, all the regions have adopted a large variety of measures to fund specific hospitals functions and activities (transplants, blood banks, Emergency Departments) and to contrast the incentives to increase the number of admissions generated by the per-case payment (ceilings on volume of care, financial penalties for organisations exceeding predefined targets, etc.)

The currently available national list includes 489 mutually exclusive DRGs (surgical and medical) grouped in 25 Major Diagnostic Categories (MDC) (Grouper 10). Variables used by the DRG-Grouper for assigning a specific case to a certain DRG are: principal diagnosis at discharge, concomitant pathologies and complications, surgical interventions, diagnostic and therapeutic procedures, age, and patient status at discharge.

In addition, the national list includes the following services without a DRG code:

1. organ transplantation
2. artificial heart implementation
3. ancillary services to parents assisting hospitalized children

Italian DRG list is explained in more detail in the section three.

To a certain extent, the DRGs system may be considered a benefit catalogue. The interventions to which surgical DRGs refer are expected to be offered and funded, at least in some patients. Therefore, surgical DRGs define a sort of list of services available to patients. For medical DRGs the situation is different as the classification includes all the possible diagnoses, including those for which hospital admissions may not been appropriate. In general, thus, medical DRGs do not define a list of services to be guaranteed, but rather economic constraints according to which providers act. Thus, although implicitly, the values of the DRGs system influences the specific content of the services provided in each diagnosis category.

In Italy as well as in other countries, fixing reimbursement tariffs to specific diagnosis and treatment is seen as restrictive to the growth of medical device markets. It may negatively impact on technology diffusion since the tariff assigned for cases treated with traditional services is not enough to cover the extra costs of a device. Therefore, the hospitals willing to provide the innovative services to their patients are forced to do so from their own budgets. This may impact negatively on the availability of a particular service since its provision will depend greatly on the hospital financial capacity. Regional authorities, however, may adopt different policy measures that will determine whether particular service will be included in regional benefit packages. This phenomenon is illustrated with one of the mostly debate issues in Italian NHS in the recent years: introduction of Drug Eluting Stents in the clinical practice (Box 1)

Box 1. Drug Eluting Stents (DES) in Italy

Since its introduction into the European market in 2002, DES has been gradually implemented into clinical practice in Italy, mainly by hospitals in the Northern regions. Several position papers and recommendations were provided by scientific societies (e.g. Italian Group for Hemodynamics Studies (GISE), study groups, local committees (e.g. Emilia-Romagna Cardiology-Cardiosurgery Committee) in order to guide the adoption of DES. Early updating of reimbursement policies has been advocated by Italian cardiologists, hospital administrators and patients in order to allow this technology to be economically sustainable by the hospitals.

Faced with continuously growing clinical and economic evidence, some Regional authorities started to adopt different policy measures. Lombardy Region, for example, revolutionized its DRG classification by creating 3 new DRGs to cover stent reimbursement and encourage utilization. Other regions (Emilia Romagna, Lazio, Marche, Puglia) allowed for particular DRG tariff increase in case the service is provided with the use of stent. Additionally, Emilia-Romagna region established a regional registry to monitor the rate of adoption of the new technology and its effectiveness in real-life conditions. The final aim being that of identifying the target populations for which the new technology would be most beneficial.

Most of the regions still have not updated in any way their reimbursement policies, limiting to certain extent the diffusion of device on their territory.

The example on DES illustrates the existence of wide variations across the Italian Regions in the amount of resources dedicated to innovative technologies. A similar situation may be also found in other sectors of health care, impacting the level and kind of entitlements available across the regions.

However, the issue is not that simple when we consider that one of the fundamental rights of Italian citizens is “freedom of choice of provider and place of care”. This right may be exercised within or outside regional boarders. Thus, regions have to pay for the treatment provided to their residents by providers located in other regions (outward mobility) and, in turn, they receive payments for the health care provided to patients coming from other regions (inward mobility).

An in-depth discussion on interregional mobility in the Italian NHS is beyond the scope of the present report. However, a few issues of particular importance for the role of health baskets in health care systems are presented in the final section of the report.

In conclusion, in Italian NHS in-patient benefits are implicitly based on a traditional view of the hospital as a main reference point for any kind of health (and sometimes social) care problem. This role of the hospital is gradually changing. The aim of the recent measures was to set the criteria for treating patients in alternative settings without jeopardizing quality of care; i.e. appropriateness has increasingly gained in its importance.

The explicit definition of “DRGs deemed at risk of inappropriateness” is the first step in that direction. The list defined at national (Governmental decree November 29th 2001) includes 43 DRGs that may be considered inappropriate if treated in ordinary hospital regime. The regions are mandated to set the “cut-off” number of admissions above which the hospitalization is to be considered inappropriate and patients should be treated in alternative settings.

Day cases of curative care

Services available in day hospital regime are defined as “diagnostic, rehabilitation and curative care”, delivered as alternative to ordinary hospitalization, when the services to be provided require, due to their nature or complexity of provision, medical or/and nurse continuous assistance, not available in the out-patient (ambulatory) setting” (Presidential decree October 20th 1992).

As for in-patient care, services available in day hospital are not explicitly defined but rather there are some specific criteria to be respected in order to consider the service appropriately delivered in this regime. Guidelines are defined at national level and they refer mostly to organizational aspects of services’ provision rather than their specific types (i.e. number of beds assigned for day hospital services must be at least 10% of the total).

Again, the approximate list of services that are provided in day-hospital regime may be found in the DRG classification. As already mentioned, all 492 DRG categories defined for ordinary hospitalization may be provided in day hospital.

As to day surgery care, the situation is very similar. In 2002 the Permanent State-Regions Conference approved national guidelines for day surgery services. The main criteria for day surgery activities are identified as: effectiveness, efficiency and appropriateness of interventions provided. In the agreement it is stated that Regions are autonomous in defining the appropriate organizational arrangements on the basis of three possible models: (i) independent specialised centre for day surgery; (ii) mono or multi specialist day surgery unit or (iii) beds within hospital departments assigned to day surgery. Furthermore, regions are free in deciding upon which services may be provided in day surgery. The final decision is made by the physician who evaluates patient clinical characteristics and organizational capacities. National guidelines provide an indication, that is a list of possible interventions that may be performed in this setting, as alternative to normal hospital care. The

list includes about 780 interventions, itemised by service delivered and grouped according to the organ or system of organs they refer to (analogous to classification of out-patient services, see below). Finally, the same agreement establishes a technical committee in charge of monitoring the day surgery care delivered in the country.

Out-patient care

Primary care

All patients in Italy are registered with a general practitioner (GP) or a paediatrician who is in charge for providing most primary care, for referring to specialists and for prescribing drugs. Patients are free to choose their primary care physician (or paediatrician) provided that the physician's list has not reached the maximum number of patients allowed. Due to the limited number of paediatricians in primary care, children are often treated by general practitioners.

Italian GPs and primary care paediatricians work as independent contractors, mainly paid on an age-adjusted per capita basis. For decades Italian GPs have generally worked in solo practices. Recent reforms introduced significant incentives in primary health care services to develop group practices and to promote integration between primary care physicians and district services such as specialised medicine, social care, home care, health education and environmental health.

Primary care services provided by GPs are outlined broadly in the National Contract for General Practitioners that represents the most important document regulating various aspects of primary care. The National Contract is a result of negotiations between the State and representatives of general practitioners organized in various trade unions. Once reached, the agreement becomes a law through a Decree approved by the Ministry of Health (i.e. the agreement is a binding by law).

In addition to the National Contract, Regions are autonomous in establishing further agreements (*Accordi Integrativi Regionali*) mainly aimed at identifying the most appropriate organizational arrangements for the provision of services set at national level. The regional agreements may define additional services to be provided in primary care, but those are not considered as part of the national benefit basket.

Thus, primary care services included in the Italian benefit basket are defined at the central level through the national contracts between the government and the trade unions representing GPs and Paediatricians.

The first objective of the National Contract with GPs signed on January 28th 2005 is set: "to guarantee the provision of essential levels of care across the national territory".

The categories of services that primary care doctors are obliged to provide under National Contract are defined broadly as:

- a) essential services: acute and chronic disease management, in line with best practice indications and in agreement with the patient;
- b) health promotion activities;
- c) patient management within programmed and integrative domiciliary care coordinated with providers of specialist and rehabilitative care services;
- d) community services defined on the basis of Regional agreements;

The National Contract also promotes and encourages various forms of integration between primary care physicians and district services such as social and home care. The services that should be provided at this level include:

- prevention and cure of drug and alcohol addicts
- health protection of infants, women and families
- protection of elderly and disabled
- services to patients affected by HIV
- protection of mental health
- services to patients suffering from chronic degenerative diseases

Furthermore, the Governmental decree that introduced and defined “essential levels of care” (Dpcm November 29th 2001, see sections 1 and 3) defines primary care services as follows:

- health education
- domiciliary and ambulatory visits (diagnostic and curative)
- drug prescription and referral to specialists
- proposals for hospitalization or thermal treatment
- consulting with specialists and access to hospital settings
- anti-influenza vaccination
- certification for school readmission and temporary incapacity to work
- certification for sport activity of scholars
- additional services included in National Contracts

All necessary services are provided through ambulatory or domiciliary visits aimed at prevention, diagnosis, treatment and/or rehabilitative care. Opening hours for ambulatory visits are decided by the GP, in line with specific indications defined in the contract (max 15 hours a week, from 8am to 8pm). Domiciliary visits are performed within the same day of patients’ request.

Additionally, the National Contract obliges the local health authorities to guarantee the continuity of care, i.e. services provided 24 hours a day, 7 days a week. Organizational arrangements are decided at regional level. These services, assessed as “non deferrable” and provided by single primary care physicians or by group practice, include: (i) referral for hospitalization; (ii) certification for incapacity to work and (iii) drug prescription. Additionally, one part of services listed in Appendix D of the contract (see below) may be provided in continuous care regime.

Appendix D of the National Contract defines “additional services” that may be provided at primary level of care. This list represents the only detailed description of services provided in primary care. The final purpose of the list is a fee schedule (for their provision GPs are paid individually, on top of their budget on per-capita basis). The services are classified in three categories: (i) services not requiring NHS authorization (first and successive medication, superficial wounds suture, threads removal, urethral catheterization (men and women), phlebotomy (only in emergency cases), tetanus vaccination);(ii) Services requiring NHS authorization (phlebotomy cycle curative cycle of endo-venous injections, aerosol curative cycle, non obligatory vaccination) and (iii)services defined by additional regional agreements.

Out-patient dental care

Definition of dental care services to be included in benefit package has always been a debated issue in the Italian NHS. Current legislation explicitly excludes all types of dental services from the nationally defined benefit package. Some limited care is available to special groups of patients defined by age and certain clinical conditions.

This explicit and rather broad exclusion of dental care services at national level had an impact on regional health policies. Numerous regions, in fact, considered various modalities in order to guarantee some types of dental care services to the citizens.

In most regions, dental services are defined explicitly, and both positive and negative lists are available. Provision of dental care is limited to special patient groups in 7 Italian Regions (Valle d'Aosta, Veneto, Liguria, Umbria, Marche, Puglia and Calabria).

In general, dental care is limited to: adolescents (14, 16 or 18 years), severely disabled, poor (with different income criteria applied in Valle d'Aosta, Veneto, Umbria, Puglia) and (only in 3 regions: Veneto, Puglia and Calabria) patients affected by specific diseases.

In most of the Regions the benefit packages does not include dental prosthesis or any other durables.

In Box 2 dental care benefits offered by the Veneto region are presented. The exclusion of dental care is still object of discussion. However, it is likely that this category of services will continue to be excluded from the nationally defined benefit package.

Box 2. Dental care services in Veneto region (defined by Regional decree 2227/02)

In Veneto region a list of dentist services is explicitly defined in a Regional decree. The list includes services available free of charge for special patient categories, while for some of them defines the co-payment amount. It is underlined that the services are available under set conditions only for the residents of Veneto Region, while non-residents must pay the full tariff out-of-pocket.

The special categories of patients are identified by age, income level, employment status and, in few cases, presence of specific disease:

- dental health care in developmental age (0-16 years): preventive, diagnostic and curative services for under 16, orthodontics care for under 12, non surgical treatment of paradental pathology under 16.
- dental and prosthetic care to very low-income residents (<€ 8500) affected by chronic (eg. cardiac insufficiency, psychosis) and rare (eg. metabolic diseases, immunodeficiency) pathologies or disabilities
- specialist curative care (excluded prosthetics) for analgic emergency cases cause by infections of caries, of paradental pathologies of traumatic events

Specialised out-patient (ambulatory) care

Specialized ambulatory services, including visits and diagnostic and curative activities, are provided either by local health units or by accredited public and private facilities. Italians are allowed to access specialist care only after approval by their general practitioner, who is responsible for the referral. Once the general practitioner has authorized the visit or the procedure, patients are free to choose their provider among those accredited by the NHS in the whole Italian territory.

The list of specialised out-patient services provided by the NHS is defined by the Decree of Ministry of Health (DM July 22nd 1996). The benefits are classified in three different sections:

1. specialist out-patient care (inclusive of clinical laboratory and diagnosing imaging) provided under NHS coverage (positive list of services, explicitly defined and enumerated, mainly without specific link to clinical conditions)
2. specialist services available only for specific clinical-diagnostic indications (positive list of services limited to special patient categories)
3. specialist out-patient care not covered by NHS (negative list)

In the first section (positive list) the document defines the tariffs used for reimbursement of providers of specialist care services. Regions are allowed to set up their own reimbursement rates (using national rates as maximum) but are not allowed to modify the list of reimbursable services. Regions, are free, however, to deliver additional specialist out-patient services for which they are financially responsible. Those services should be marked separately in a fee-schedule and added to the list in accordance with the coding system in place.

Since its approval in 1996, the fee schedule defining out-patient specialist services has not been updated at national level. Almost all regions, however, have been continuously updating regional documents with the main objective to modify the tariffs applied without significant changes on the types of services provided.

Positive list (section 1) of specialist out-patient services is itemized by service delivered. The services (approximately 2000) are grouped in 16 chapters on the basis of system of organs the intervention refers to (Figure 4). Each category is further divided in subcategories according to the specific organ. Finally, each sub category contains a list of specific services.

Furthermore, some services in the positive list are limited to special settings (with specific equipment or with particular status).

Services that are only available to special patients categories (i.e. limited for specific clinical conditions) are explicitly labelled with an asterisk and reported in the second section of the document. This second list contains about 20 items, mainly laboratory and diagnostic exams that are very costly (e.g. PET) or somehow controversial (palliative pain treatment).

All other out-patient curative care (ergotherapy, logopedy, chiropody, podiatry; alternative & complementary medicine)

Physiotherapy

Numerous services of physiotherapy are excluded from the national benefit package (see section I). Many regions, however, have approved their inclusion in the regional benefits so to generate substantial variability across the country. Lombardy, for example, includes all services listed on the national negative list while Veneto and Friuli authorize "water-rehabilitation". Almost all regions provide analgic electrotherapy, ultrasound therapy, mesotherapy and laser therapy.

Alternative and complementary medicine

The National benefit package explicitly excludes all types of alternative and complementary medicine (see section I), leaving to Regions to decide whether to provide some of those services to their citizens. Only 4 out of 21 regions, however, have invested in this category of services:

- acupuncture is available in Piedmont, Valle d'Aosta, Umbria and Tuscany
- homeopathy is available in Valle d'Aosta (limited for specific clinical conditions)
- chiropractic services are available in Valle d'Aosta only for spinal cord pathologies

Thermal (Spa) treatment

Spa treatment is available for limited number of pathologies, identified as those for which thermal treatment may provide actual benefits (based on scientific evidence). The list of pathologies is explicitly defined in the Ministry decree approved on December 12th 1994 and includes, among others: rheumatic diseases: osteoarthritis and other degenerative forms; extra joint rheumatisms; respiratory diseases: chronic pulmonary diseases (obstructive or not); dermatologic diseases: psoriasis; gynaecological diseases; vascular diseases..ecc).

Services of rehabilitative care

(in-patient rehabilitation, day cases, out-patient rehabilitative care, home care)

The decree defining the national benefit basket explains rehabilitative care in a rather vague manner. A somewhat more specific description of services is provided in the Guidelines for rehabilitative care issued by the Ministry of Health in 1998. Those guidelines try to distinguish between rehabilitative "health" and "social" care. Rehabilitative healthcare includes all services (curative, diagnostic, evaluative) and other procedures aimed at minimizing disability after acute episodes, assisting the individuals to walk, talk, dress, eat and communicate effectively in his/her own private, professional, school and social environment.

Rehabilitative healthcare is classified according to the level of intensity and complexity of healthcare services and resources required to provide those services in two broad categories:

- 1) extensive and intermediate rehabilitative care
- 2) intensive rehabilitative care

Overall rehabilitative care is provided through the network of different settings of care (called "organizational levels"):

- in-patient: ordinary hospital admission or day hospital
- residential, i.e. nursing home (*Residenza sanitaria assistenziale-RSA*);
- out-patient (ambulatory) and domiciliary (home care)

Intensive rehabilitative care is delivered only in in-patient settings, with specific appropriateness criteria for ordinary hospital admissions and day hospital.

Extensive and intermediate care may be provided in all three levels of care (in-patient, out-patient, domiciliary) in various health and social care institutions (hospitals, specialist ambulatories, RSA, residential and semi-residential institutions, social centres, patients' home). Specific services guaranteed to citizens at each level are not specifically defined, but their inclusion in the health basket is rather implicit. This is particularly valid for in-patient and residential setting for which there is no specific benefit catalogue defined, but everything deemed necessary and appropriate at a given level is delivered to patients. There is some difference for out-patient rehabilitative care, for which there is an explicitly defined list of services that is provided in ambulatory regime. This list makes up one category of complete out-patient fee schedule (see section 3 and paragraph on specialist out-patient care in this section). The *category Physical therapy, Respiratory therapy, Rehabilitation and correlated services* includes approximately 100 services, listed by items without specific link to clinical indications.

Even though the national fee schedule contains all out-patient services, the national benefit basket explicitly excludes some physiotherapy and rehabilitative care services delivered in out-patient regime, for example: assisted exercise in water, idromassoterapia, antalgic laser and electro therapy, mesotherapy, ultra-sound therapy...ecc.

Almost all regions (except Emilia Romagna, Umbria and Calabria) have included most of the services in the national negative list in regional benefit packages, limited their availability to special categories of patients (specifically defined in only 12 Regions).

Medical goods dispensed to out-patients

Pharmaceuticals

Since the introduction of the NHS in 1978, pharmaceutical products available under public coverage has been explicitly listed in the positive list.

In 1994, the pharmaceutical sector's regulatory environment was radically changed. Regulatory power was concentrated within a national technical body CUF (Commissione Unica sul Farmaco) that was mandated to introduce a new set of measures in order to reduce public pharmaceutical expenditure. These measures included a radical redefinition of both the positive list and cost sharing rules. Since its foundation, the CUF has become a dominant regulatory body of Italian pharmaceutical policy, in charge of various functions including drug licensing, expenditure monitoring, price settings and NHS coverage.

The Financial Law for the year 2003 instituted the Italian Drug Agency (AIFA- Agenzia Italiana del Farmaco) starting from 2004. AIFA was given all competencies on drug policy, including jurisdiction over drug licensing and the definition of the positive list .

AIFA is organized in 5 distinct scientific areas with respective responsibilities:

- drug licensing and pharmaco-surveillance
- production control
- information and clinical research
- pricing, reimbursement, market analysis, research & development
- European procedures assessment (centralised and mutual recognition approval procedures)

The Agency is governed by a five-member board appointed by Ministry of Health (three) and the State-Regions Permanent Conference (two). AIFA is also supported by 4 scientific commissions composed by experts in the field:

- a) Technical-scientific Commission (CTS, ex-CUF): evaluates and consults on drug licensing (through national and centralised procedures), classifies drugs for reimbursement;

- b) Pricing and Reimbursement Commissions (CPR): negotiates with the industry the prices of reimbursable drugs in line with timelines and procedures set by Inter-Departmental Committee on Economic Planning (CIPE);
- c) Commission for relations between AIFA and the Regions: analyses national and regional pharmaceutical expenditure;
- d) Commission for R&D promotion

Only the first two Commissions, however, have been activated so far.

Almost simultaneously with changes in the regulatory environment, the 1994 positive list was modified. Since January 16th 2003 (Law n.178, August 8th 2002; Decree December 20th 2002 all pharmaceuticals are classified in two categories:

- class A: pharmaceuticals fully reimbursable by NHS
- class C: pharmaceuticals not reimbursable by NHS

The new positive list (class A) is defined on the basis of: i) risk-benefit profile of the therapy (clinical efficacy, as documented by controlled clinical trials, pathology relevance in terms of severity and diffusion, side effects in relation to expected benefits); ii) relevance of the disease (minor diseases are excluded) and iii) cost of therapy.

Thus, the positive list includes only one category of drugs fully covered by NHS. At present there is no co-payment on pharmaceutical determined at national level. However, regions can introduce user charges limiting the reimbursability of drugs listed in national formulary.

All pharmaceuticals in the positive list (class A) are issued only on medical prescription, while class C includes both pharmaceuticals with and without prescription requirement. Over the counter drugs (OTC) belong to class C and, therefore, are not reimbursed by NHS at all.

In addition to classes A and C, a special group of pharmaceuticals is labelled as class H and includes hospital-only drugs, i.e. distributed only in hospital settings under specialist supervision. Pharmaceutical products consumed or dispensed in hospitals are fully reimbursed whatever the reimbursement status.

With regards to pharmaceuticals included in the positive list (reimbursable by NHS) the decision power is concentrated in the Pricing and Reimbursement Commission- a technical body with 12 expert members (5 nominated by the Ministry of Health, 5 nominated by the Regions, 1 from Ministry of Economy and 1 from Ministry of Production Activities). AIFA executive board formalizes the final decision of the Commission (see Figure 2).

Drugs available under public coverage are listed in the National Pharmaceutical Formulary (NPF) that is revised annually. More specifically, Law n.326, November 24th 2003 mandates the AIFA to define on annual basis (by September 30th or every six months in case of pharmaceutical budget overrun) the list of pharmaceuticals in the NPF. The main objective of NPF revision is to control and ensure annual expenditure levels agreed between the Government and the Regions.

The spending cap on pharmaceuticals was newly introduced in 2002 as a 13% of total health care spending. Regional Governments were initially allowed to completely delist drugs in order to meet the 13% cap. Delisting power was brought back on central level in November 2002 and only cost sharing on reimbursable drugs has remained in the hand of regions.

The last two revisions of the NPF conducted in 2003 and 2004 explicitly referred to cost-criterion for redefining the positive list. In 2003, cost of therapy was used for defining the reimbursement level (cut-off) within homogenous therapeutic category. This classifications was used to introduce new reimbursability rules for

about 20% of drugs: therapeutic classes were chosen on the basis of their clinical relevance and epidemiological and financial impact.

A homogenous therapeutic category is defined as “a group of drugs that, in relation to the main therapeutic indication share the same action mechanism and are characterised by more or less the same clinical efficacy and profile of adverse events. Individual drugs, however, may differ in terms of additional therapeutic conditions”. Homogenous therapeutic categories, introduced in 1999, basically correspond to the fourth level of the ATC classification. For each category, a cut-off price is defined: higher prices automatically imply the exclusion from the positive list (no NHS coverage).

In 2004 the cut-off principle was not applied, but differentiated price cuts were mandated for certain number of products. More specifically, in order to keep the expenditure below the spending cap, price cut was applied to 56 active principles (294 packages) whose increase in expenditure in first semester of 2004 was significantly higher than the national average (+8.6%). In case the producer did not accept to cut the product price, drug would be excluded from the positive list.

Other explicitly declared criteria for defining and up-dating national positive list of pharmaceuticals are summarized as follows:

- a) to ensure the complete coverage of all clinically and epidemiologically relevant pathologies;
- b) to ensure General Practitioners the possibility to choose among different active substances having the same therapeutic indication;
- c) to identify the reimbursement value in order to save money by trying to minimize market price variability among molecules having comparable efficacy and tolerability.

In the latest version of NPF (NPF 2005) 4475 drug packages are included in the positive list, for a total of 723 different active principles. In comparison to the previous version, NPF 2005 contains 58 new active principles (drugs for AIDS, hepatitis B, osteoporosis, atopic dermatitis, haemophilia, rare diseases).

GPs and specialists acting as NHS doctors may prescribe any drug from the positive list provided that specific restrictions do not apply. These specific restrictions are defined in a special document named *Prescription Notes*.

Prescription Notes (previously called CUF Notes nowadays AIFA Notes) are a set of compulsory guidelines restricting the reimbursability of drug to specific diseases or patients' conditions. These notes define specific illnesses for which some groups of pharmaceuticals present in the positive list are reimbursable by the NHS. In other words, inclusion in the NHS basket of some drug categories listed in the NPF is limited, i.e. those categories are covered by NHS only if prescribed for certain conditions.

In general, certain drugs may be subject to Note limitations when:

- they are authorised for different indications, out of which only some are relevant pathologies;
- they are used for prevention purposes relevant only for specific population groups (targeted groups)
- they are used not only for indications for which its efficacy is proven, but also for conditions for which evidence is not sufficient (risk of inappropriate prescription)

Clinical indications listed in the *Notes* are identified on the basis of solid scientific evidence on drug efficacy coming from randomized controlled trials. The main scope is to orient GP prescribing behaviour towards more effective and more experimented molecules. In this sense, the *Notes* represent a clear example of explicit use of evidence based medicine in defining goods to be included in NHS basket. For example, the Note n.13 (cholesterol-lowering drugs) defines that active principles included in the positive list can be provided under public coverage only if prescribed for specifically defined clinical conditions and not widely available for any kind of cholesterol disorder.

In principle, since 1996 doctors have been liable to sanctions if they do not respect the Notes.

Since their introduction in 1994, the Notes have been revised several times. The latest version of AIFA Notes was approved in November 2004. Before final approval the current version of the Notes was discussed with representative of various "stakeholders" (doctors, pharmacists, producers, patients).

The document consists of 41 notes with major ones referring to lipid-lowering agents, anti-ulcer drugs, injective antibiotics and non steroid anti-inflammatory drugs.

Therapeutic appliances and other medical durables

The Italian national benefit basket explicitly includes "provision of prosthesis, orthopaedic and technical appliances to disabled". The specific list of appliances covered by the NHS is provided in a separate document (Decree 332/1999) that contains the complete list of goods (and corresponding reimbursement tariffs) and their indications for their appropriate delivery. In addition, a separate section of the document defines the categories of patients to whom the appliances can be provided under NHS coverage (without references to which types of prosthesis or orthopaedic appliance), among which: civil and war invalids, blind and deaf-mutes, minor (less than 18 years of age) who require the prosthetic care for prevention purposes. Appliances for work invalids are provided and funded by the National Insurance Institute for Work Accidents (INAIL).

Overall prosthesis, orthopaedic and technical aids are divided in different classes according to ISO classification (EN ISO 9999). Each class contains a very detailed description of the appliances and their technical characteristics (over 200 pages). The appliances are labelled according to their production characteristic (serial or ad hoc).

Table 2. Therapeutic appliances and other medical durables- classification adopted in the Italian NHS basket

Class		Examples of appliance categories
03	Curative And Training Aids	Aids for hernia treatment
06	Prosthesis And Orthosis	Spinal orthosis Upper- and lower limb orthopaedic aids Upper and lower-limb prosthesi Orthopaedic shoes
09	Aids For Personal Care And Protection	
12	Aids For Personal Mobility	Wheelchairs Bicycles Vehicles Lifting aids
15	Aids For Home Care	
18	Adaptations For Patients Home Environment	Aids for sting positions
21	Aids For Communication And Information	Optical aids Hearing aids
24	Aids For Handling Objects	
27	Environmental And Car Adaptations	
30	Aids For Leisure Time Activities	

Prevention and public health services

The Italian NHS provides for a range of services for prevention of communicable diseases, explicitly defined in a positive list. It includes collective and individual measures. Collective measures include the following services: infectious disease control, prophylaxis, health education and surveillance of activities for disinfection, disinfestations and eradication. Individual measures include obligatory and recommended vaccination (immunization).

The local health unit is primarily concerned with protecting and promoting public health and is responsible for achieving the health objectives and targets established by national and regional planning. Each local health unit has a health promotion department in charge with the provision of all public health services.

The Italian legislation has never detailed the list of preventive and public health services. The only list available is provided by the Governmental decree defining the national health basket (DPCM November 29th 2001). It identifies categories of services grouped in two classes.

1. community (general public) prevention (inclusive of occupational health care);
2. individual prevention services.

Community prevention services include:

- a) hygiene and public health, including infectious and parasitic disease prophylaxis, health promotion and education and preventing environmental hazards
- b) food control (production, processing, preservation, commerce and transport),
- c) preventing food-related disease and nutritional surveillance (preventing obesity and malnutrition, etc.);
- d) preventing occupational diseases and accidents;
- e) veterinary medicine (surveillance of animal stock health, hygiene of food production and animal food safety and control).

Individual prevention services include:

- a) mandatory and recommended vaccination (defined by the national vaccination plan)
- b) programs aimed at early diagnosis (no national screening programme exists, as regions are responsible for disease prevention activities; regional initiatives focus primarily on screening for breast and cervical cancer).

Maternal and child health

Services available to this category of patients are included in the national benefit package within a broader category of health and social care services for women, couples and families. Those services include family planning and counselling, reproductive health (maternal care, birth, abortion, contraception) explicitly listed in the positive list (for further detail see section on Integrated health and social care).

Furthermore, the National Project "Maternal and child health" (approved by Ministry Decree on February 14th 2001) identifies appropriate organizational arrangements in order to provide adequate care to these categories. The services listed include: transportation of mothers and new-borns, in patient care for children (inclusive of emergency services); rehabilitation care.

As to IVF, there have been some significant changes in the Italian legislation in 2004. Present legislation allows for IVF under public coverage only to heterosexual couples who use their own gametes (external donators are therefore excluded as well as women who offer to carry out pregnancy for someone else).

Ancillary services to healthcare

Patient transport and emergency rescue

This category of healthcare services is included in the national benefit basket under "Territory emergency care" of "Community care services" as defined in DPCM 2001.

Services guaranteed are broadly defined as:

- response to requests for intervention and coordination of activities within the community
- basic and advanced assistance outside the hospital
- patient transportation in adequately equipped ambulances

Other miscellaneous services

Within "Supplementary care services", the national health basket includes additional services for special categories of patients. These categories are defined by following pathologies:

- diabetes: free supply of diagnostic solutions for glucose-testing and other material;
- rare diseases: special diagnostic and monitoring services;
- cystic fibrosis: free supply of medical material and pharmaceuticals necessary for treatment and rehabilitation
- Hansen's disease: free supply of diagnostic services and pharmaceuticals (included those not available in the Italian market); travelling expenses for prophylaxis and treatment;

Special area-mental health care

The most important change in the mental health care in Italy, as in many Western countries, has been the decision to shift mental health services from psychiatric hospitals into the community. In Italy, the process of de-institutionalisation was introduced by a specific mental health legislation that adopted community approach to psychiatric care.

The 1978 reform (Law 180) established Community Psychiatric Services in order to provide comprehensive care to populations residing in defined geographical areas. This legislation banned new admissions to public psychiatric hospitals and devolved to regions the responsibility of managing the transition towards community psychiatric care. Wide variations across regions in the amount of resources devoted to community psychiatry were registered in 80s but gradually diminished in the 90s.

At present there is not a specific list of mental care services that make part of health basket. The most relevant document that regulates this special area is the Presidential decree n. 274/1999 that adopted the National Project "Mental health care 1998-2000". The document introduced Mental Health Departments as coordinating bodies to guarantee integration of psychiatric services within a certain territory. Each local health care authority had to establish a Mental Health Department with the following organizational components:

- Mental Health Centres;
- Psychiatric diagnostic and curative centre (a mental health unit in the general hospital);
- Day hospital;
- Day center
- Residence (nursing home) for therapeutic and social rehabilitation

Article 7 of the document obliges the Mental Health Departments to provide "services chapters", i.e. to prepare and distribute catalogues of services available that should include, among other information, the following: description of existing providers (with relative modalities of access), description of department priorities and principal activities performed.

In addition, the document describes broad categories of services available at each provider level.

Mental Health Centres are in charge to assure access to diagnostic services, to define and implement therapeutic-rehabilitative and socio-rehabilitative programs through integrated approach with other providers of health and social care; to provide specialist consultancy for "boarder line" services (alcohol and drug addicts, nursing homes for elderly and disabled) to gatekeep for hospitalizations and to monitor hospital admissions in private neuro-psychiatric institutes in order to ensure continuity of care. Mental Health Centre must be active 12 hours a day, 6 days a week. Mental Health Centres are supposed to keep the overall responsibility for the patients and to coordinate the interventions performed by the providers.

Psychiatric diagnostic and curative centres are situated within general public hospitals, and are in charge of in-patient services. They are supposed to be used for acute phases only and have a maximum capacity of 16 beds..

Day hospitals provides diagnostic, curative and rehabilitative care services in a semi-residential regime. Its main activities are to provide medical treatments and to avoid the use of regular admissions.

Day centres is a semi-residential institution that provides curative and rehabilitative care services in the community;

Residences are extra-hospital units that supply part of the therapeutic-rehabilitative and socio-rehabilitative programs with exclusive competencies in psychiatric services.

In conclusion, an explicit list of mental care services does not exist in Italian NHS. The national legislation rather provides "an organizational framework" of various providers who ensure the availability of public services. The main emphasis remains on integration between different types of care (hospital, outpatient, domiciliary, social and rehabilitative care).

Integrated area of health and social care

Integration and improved coordination of health and social care have been strongly promoted by the central government for years. The National health Plan 2003-2005 identifies among objectives to be pursued: "to promote an integrated network of health and social care services to chronically ill, disabled and elderly". The emphasis on integration is aimed at fostering the move from long-stay institutional care to community. This is particularly important for special categories of patients who may require help over long periods of time (elderly, chronically ill, severely disabled).

Legislative Decree 299/199 establishes the initial framework regulation required to promote cooperation among social and healthcare providers which focused on defining the list of services to be provided through such collaboration schemes. The Legislative Decree identified three types of services located at the interface between social and health care: health care services with social relevance (to be provided under the leadership of local health units), social services with health relevance (led by municipalities) and a third group of services characterized by advanced integration of social and health care activities (to be provided jointly by municipalities and local health units).

A Ministry decree on “the coordination on health and social care services”, approved in 2001, provides operating definitions for these services and indicates the following criteria: nature of need, complexity, intensity and duration of care.

Governmental decree adopted on November 29th 2001, following the agreement between State and the Regions, further regulates this area.

More specifically, the document provides a list of broad categories of services available in the national health basket and, for particular types of services, defines the division of costs between the NHS and municipalities (or patient).

The document displays a “summary table” of health care services, health care services with social relevance, and services for which the two components are non distinguishable. From the table, it can be concluded that all long-term nursing care services as defined in the OECD classification (in-patient, out-patient, day cases as well as home care) are included in the Italian health basket within this special “on the edge” area between health and social care.

The services are organized in four macro-levels, according to criteria of care location:

- 1) community out-patient and home care
- 2) semi-residential community care
- 3) residential community care
- 4) penitentiary care

Each macro-level is further divided into various micro-levels according to the categories of recipients of care: minors, women, families, elderly, disabled, psychiatric patients, alcohol and drug addicts, terminally ill and AIDS patients. Finally, at each micro-level a specific list of service categories is provided. The categories are based on the type of services (for example: diagnostic, curative) (Table 3)

Table 3. Classification of services with integrated area of social and health care in Italian basket

MACRO-LEVELS	MICRO-LEVELS	SERVICES
<p>Community out-patient and home care</p>	<p>1) Integrated and programmed home care</p>	<p>a) domiciliary primary and paediatric care b) specialist home care c) nursing home care d) rehabilitative home care e) auxiliary nursing care f) pharmaceutical and prosthetic care</p>
	<p>2) Reproductive health and social care services for women, adolescents, couples, families</p>	<p>a) specialist, psychotherapeutic, psychological, diagnostic and curative care services (inclusive of families with adopted children) b) rehabilitative and socio-rehabilitative care to adolescents</p>
	<p>3) Health and social care services for psychiatric patients and/or their families</p>	<p>Out-patient, rehabilitation and socio-rehabilitative home care</p>
	<p>4) Health and social care services for drug addicts and/or their families</p>	<p>a) specialist treatments and therapeutic-rehabilitative services b) rehabilitative and social educative programs throughout the period of dependency</p>
	<p>5) Health and social care services within rehabilitative programs for physically, psychologically and sensorially disabled</p>	<p>a) out-patient, rehabilitative and socio-rehabilitative home care services b) prosthetic services</p>
	<p>6) Health and social care services for terminally ill</p>	<p>Palliative outpatient and home care</p>
	<p>7) Health and social care services for AIDS patients</p>	<p>Outpatient and home care services and treatments</p>
	<p>1) Health and social care services for psychiatric patients and/or their families</p>	<p>Diagnostic, curative, rehabilitative and socio-rehabilitative care provided in semi-residential regime</p>
	<p>2) Health and social care services within rehabilitative programs for physically, psychologically and sensory disabled</p>	<p>a) Diagnostic, curative, rehabilitative and socio-rehabilitative care provided in semi-residential regime b) Diagnostic, curative, rehabilitative and socio-rehabilitative care for severely disabled provided in semi-residential regime c) Reimbursement for services abroad for rehabilitation programs in highly specialized centres d) Diagnostic and curative services to adolescents with behavioural disorders or neuropsychiatric pathologies</p>

Residential community care	3) Health and social care services for drug addicts	residential regime b) rehabilitative and social educative programs throughout the period of dependency
	4) Health and social care services with rehabilitative programs for elderly	Curative care, functional recuperation and maintenance of non self-dependent in semi-residential regime (inclusive of interventions for alleviation) Diagnostic, curative and rehabilitative services in semi-residential regime
	5) Health and social care services for AIDS patients	
	1) Health and social care services within rehabilitative programs for psychiatric patients and their families	a) diagnostic, curative, rehabilitative and socio-rehabilitative care in residential regime b) curative and socio-rehabilitative services in institutions with low care intensity
	2) Health and social care services within rehabilitative programs for physically, psychologically and sensorial disabled	a) Diagnostic, curative, rehabilitative and socio-rehabilitative care provided in residential regime (inclusive of minimally responsive subjects) b) Diagnostic and curative services to adolescents with behavioural disorders or neuropsychiatric pathologies c) Curative and socio-rehabilitative care for severely disabled and for disabled without family support d) Reimbursement for services abroad for rehabilitation programs in highly specialized centres
	3) Health and social care for drug addicts	a) specialized and therapeutic-rehabilitative care in residential regime b) rehabilitative and social educative programs throughout the period of dependency
	4) Health and social care services within rehabilitative programs for elderly	a) curative care and functional recuperation for non self-dependent in intensive and extensive phases b) curative care, functional recuperation and maintenance of non self-dependent in residential regime (inclusive of interventions for alleviation)
	5) Health and social care services for AIDS patients	Curative, rehabilitative services, pharmaceutical treatments in the long-term residential care Palliative residential care services
	6) Health and social care services for terminally ill	Curative, diagnostic, rehabilitative care for addictions and mental disorders
	Health and social care services to prisoners	

Penitentiary care		
--------------------------	--	--

3. DESCRIPTION OF BENEFIT CATALOGUES, INVOLVED ACTORS AND DECISION CRITERIA

A) Decreto del Presidente del Consiglio dei Ministri (DPCM) November 29th 2001

The overall content of the NHS benefit package is defined in a Governmental decree approved on November 29th 2001. The decree followed the agreement reached between the State and the regions on August 8th 2001. This act was prepared and agreed by the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces. The original purpose of the document is to define entitlements to be guaranteed to citizens across the country.

The Standing Conference was set up in 1988 and it is the main consultative body for all the legislative activities which have an impact on regions. It can promote collaboration schemes across regions and the central government and can propose new legislation. Since its establishment, the Conference adopted more than 1800 legal acts in various sectors of the society.

Currently the Conference is made of 22 members (20 presidents of the regions and 2 of the autonomous provinces). It is directed by the National Minister for Regional Affairs who can invite other representatives of the central government. With regards to agreements reached on the national benefit basket, the Ministry of Health and the Ministry of Treasury actively participated in the decision making process. Patients and citizens representatives are not involved in the process.

According to the agreement on the national basket, its content was defined in accordance with available resources at central level; therefore, the overall budget available determined the overall limits of the basket. Other criteria, although not explicitly stated in the document, referred to need effectiveness and costs of healthcare interventions.

Overall, the document is divided in three sections:

- 1) services included in the benefit package
- 2) services partially included in the benefit package
- 3) services excluded from the national benefit package but that can be provided by regions with their own resources.

Section one lists all service categories under public coverage. Overall, the benefit catalogue refers to three macro levels of care (Figure 3):

- A. public and occupational health services
- B. community care
- C. hospital care

In addition to three macro levels, supplementary area of care for special patient categories is defined in the document.

Each of the three categories is divided in micro-levels which are further sub-divided in individual services or group of services. Where available, the legislation sources are identified for each micro-level or group of services. In fact, the decree represents "simple" re-organization and categorization of already active decrees, laws, fee schedules and other documents defining services guaranteed to citizens. Consequently the level of detail and explicitness of services is very different between the three macro-levels (Figure 3). For example, public and occupational health services category provides detailed list of guaranteed functions, in some cases, organized in chapters. Chapters in "Hygiene and public health" are defined according to areas of interventions (prophylaxis, reduction of health risks associated with environmental pollution and other environmental factors), while "Veterinary public health services" include chapters on the basis of production phases of animal food products.

On the other end, hospital care is very broadly defined in 7 chapters of care without any number of items provided. It is actually explicitly recognized that in Italian legislature there is no list of services provided in the hospital.

As to Community care, DPCM doesn't provide any further level of detail for different sectors of care (primary care, pharmaceuticals, specialist outpatient care..ecc), but legislative sources and references where those information may be retrieved (if available). Thus, DPCM refers to National Contract for primary care, National Pharmaceutical Formulary for

availability of pharmaceuticals, Prosthetic fee-list and so on. The level of detail available for each category differs greatly across these documents (see below).

The document described refers to its first version (approved in 2001) which is currently in force. It is foreseen that the decree should be up-dated on a regular basis. Since its approval, however, significant up-dates haven't been undertaken. Only a minor revision was approved in 2003. Recently (February 2004), the Ministry of Health established the Committee for up-dating and defining benefits to be included in the national basket. The criteria to be used are resources available and scientific evidence. The Committee is directed by the Ministry of health and is composed of 14 experts in healthcare policy, planning, management and medicine. They are appointed by regions (7) the Ministry of Health (6) and the Ministry of Economy and Finance (1). The most urgent objective set for the Committee is to define clinical indications for appropriate provision of services listed in section 2 of the 2001 governmental decree. Furthermore, the list of services currently included in the benefit basket (section 1- Specialist out-patient care; Prosthesis services) would be up-dated. Until today, the Committee has not made any decision.

B) Legislative Decree of December 14th 1994 "Introduction of DRG reimbursement system for hospital care in Italy"

It was mentioned earlier that Italian DRG system introduced in 1995 is equivalent to the US DRG reimbursement scheme according to HCFA Grouper version n.10. Consequently, national list contains 489 DRGs in 25 MDC (Table 4).

A DRG Grouper is a computer program or module which takes those 5 clinical and demographic data as input and gives a corresponding Diagnosis Related Group as output. The diagnoses and procedures are encoded as ICD9cm codes (International Committee on Diseases, version 9, Clinical Modifications).

Variables considered for assigning a case to a particular DRG (HCFA-DRG Grouper n.10) and their relative importance are presented in the table:

Total number of valid DRGs	489	
Only principal diagnosis and/or surgical interventions	335	68.5%
Age	44	9.0%
Concomitant pathologies and complications	103	21.1%
Status at discharge	6	1.2%

General logic behind patients grouping can be summarized as follows (Figure 4): each hospitalization is initially attributed to a appropriate MDC on the basis of principal diagnosis at discharge (ICD classification).

Exceptional cases are assigned, irrespective of the major diagnosis, to 4 DRGs and 2 so-called pre-MDCs. Such cases include: liver transplantation (DRG 480), bone marrow transplantation (DRG 481), tracheotomy (DRG 482 and 483). Finally, peculiar combination of primary principal and secondary diagnosis define two pre- MDC: multiple trauma (MDC 24) and HIV infections (MDC 25).

Then, the Grouper distinguishes between medical and surgical DRG on the basis of existence of diagnostic/curative interventions or surgical procedure. Only "relevant" interventions, i.e. "operating room procedures" are considered in assigning surgical DRGs. On the other hand, numerous "minor" interventions, a frequent cause for ordinary hospitalizations in Italy, are not taken into account.

In case of multiple procedures while in hospital, surgical DRG is determined by the procedure that requires major consumption of resources, according to hierarchical order within each MDC. For example, hierarchy for surgical interventions and operating room procedures in MDC 2 (Diseases and disorders of the eye) is:

- 1) Interventions on retinae
- 2) Interventions on orbit
- 3) Intraocular interventions (except on retinae, iris and lenses)
- 4) Interventions on lenses
- 5) Extra ocular interventions
- 6) Interventions on iris

While MDC is assigned to a specific case on the basis of principal diagnosis, a list of interventions/procedures recognized by the Grouper is unique. Thus, different DRGs may be assigned to the same procedure.

Medical DRGs are mainly assigned on the basis of principal diagnosis, already used to determine the MDC.

Surgical and medical DRGs are further defined on the basis of other variables considered by the Grouper (age, concomitant pathologies, status at discharge).

Cases that cannot be grouped under a specific category are assigned to Residual DRGs.

Table 4. Overview of 25 MDC and number of DRGs included

MDC	Description	Number of DRGs		
		Surgical	Medical	Other
	Liver, bone marrow transplantation, tracheotomy	4		
24 (pre-MDC)	Multiple trauma	3	1	
25 (pre-MDC)	HIV infections	1	4	

1	Diseases and disorders of the nervous system	8	27	
2	Diseases and disorders of the eye	6	7	
3	Diseases and disorders of the ear, nose, mouth and throat	15	11	
4	Diseases and disorders of the respiratory system	3	26	
5	Diseases and disorders of the circulatory system	19	25	
6	Diseases and disorders of the digestive system	23	17	
7	Diseases and disorders of the hepatobiliary system and pancreas	11	17	
8	Diseases and disorders of the musculoskeletal system and connective tissue	28	22	
9	Diseases and disorders of the skin, subcutaneous tissue and breast	14	14	
10	Endocrine, nutritional and metabolic diseases and disorders	9	8	
11	Diseases and disorders of the kidney and urinary tract	14	18	
12	Diseases and disorders of the male reproductive system	12	7	
13	Diseases and disorders of the female reproductive system	13	4	
14	Pregnancy and childbirth	6	9	
15	Newbornes			7
16	Diseases and disorders of the blood and blood forming organs	3	5	
17	Myoproliferative diseases and disorders	6	9	2
18	Infectious and parasitic diseases	1	8	
19	Mental diseases and disorders	1	8	
20	Alcohol/drug use and alcohol/drug use induced organic mental disorders			5
21	Trauma and poisoning	5	12	
22	Burns	3	2	1
23	Factors that impact health status and demand for health care services	1	6	
	Residuals			5
TOTAL		211	258	20

Sixteen regions introduced DRG systems soon after the adoption of national list in 1995. Emilia-Romagna, Abruzzo and Autonomous Province of Bolzano implemented DRG system in 1996 while Basilicata and Autonomous Province of Trento followed in 1997.

A recent survey conducted by Ministry of Health showed that 10 Italian regions use Grouper version 10, 9 regions Grouper version 14 while only one region adopted version 19. Concurrently, only Lombardy uses ICD-9-CM-2002 while rest of the country applies ICD-9-CM.

The situation is constantly changing and several regions are in the process of adopting the newest version of the DRG Grouper n.19.

Table 2 represents some characteristics of 14 regional DRG reimbursement schemes (that approximately cover more than 90% of public market).

Table 2. DRG reimbursement schemes in 14 Italian regions

Region	Reference to national DRG list	HCFA version	Grouper	Number of DRGs	Year of latest update
Abruzzo	Yes	n.10		489	1999
Campania	Yes	n.10		489	2000-2001
EmiliaRomagna	No	n.14		492	2001-2002
Friuli V.G.	Yes	n.10		489	2002
Lazio	Yes	n.10		489	2000
Liguria	Yes	n.10		489	2002
Lombardia	No	n.19		506	2005
Marche	Yes	n.14		492	2002
Piemonte	Yes	n.14		492	2002
Puglia	Yes	n.10		489	2000
Sardegna	Yes	n.10		489	2001
Sicilia	No	n.10		489	2002
Toscana	No	n.14		492	2005
Veneto	No	n.14		492	2001

C) Ministry Decree (DM) July 22nd 1996 "Specialist ambulatory services"

The list of outpatient services, inclusive of diagnostic procedures, specialist visits and laboratory tests to be delivered by the NHS, was drawn up in 1996. The document was included in a Ministry decree approved on July 22nd 1996. Since then, the list of services hasn't been updated.

Although the national list hasn't been updated since its adoption in 1996, regional authorities have often revised their fee-schedules. These updates mainly refer to the reimbursement fees, while the list of services available hasn't changed significantly.

The general structure of the catalogue was decided through political negotiations at central level. It is not clear how much decision makers relied on outside expertise. The patient/citizen representatives were not officially consulted or involved into the process.

The main criteria, publicly stated as used for including services in the positive list are effectiveness (based on solid scientific evidence) and costs. Economic implications are explicitly discussed in defining the benefit catalogue, since the original purpose was to define national fee schedule.

The recently established National Committee for health basket revision (Ministry Decree October 25th 2004) has put "Specialist out-patient care" among areas of care that require the most urgent up-date. Their expertises cover mainly health management, planning and health economics field. Inclusion of patients'/ citizens' voice is not foreseen. The Commission, however, still hasn't modified the list of out-patient services. Thus, at present the national list refers to the one adopted by Ministry Decree on July 22nd 1996.

As described in section 2, the document refers to 3 categories of services:

1. specialist out-patient care (inclusive of clinical laboratory and diagnostic imaging provided under NHS coverage-positive list)
2. specialist services available only for specific clinical-diagnostic indications
3. specialist out-patient care not covered by NHS (negative list)

Section 1 includes more than 1700 services available under public coverage, most of them listed as items without any restrictions related to patients' conditions. Approximately 20 services, however, are distinguished (marked with "**") as available only for special clinical conditions. Those services are listed again in the section 2 of the same document.

Some (approximately 100) services in section 1 are labelled with "H", indicating that they must be provided only in special "protected" settings, i.e. ambulatories located in hospitals. In addition, the decree defines a list of diagnostic services that should be conducted in special laboratories authorised by Regions (around 140 service labelled with "R").

The overall structure of the ambulatory care services included in the positive list is presented in Figure 5.

D) National Pharmaceutical Formulary

The main actors involved in the decision making process concerning the National Pharmaceutical Formulary (NPF) are extensively described in the previous section. In the present chapter, we briefly summarize it and provide a description of the current positive list of pharmaceuticals (NPF 2005) together with the criteria used for its definition.

The present NPF was adopted in early 2005 by the recently established National Drug Agency (AIFA). Law n. 326 adopted on November 24th 2003 obliges AIFA to update and review the national positive list on an annual basis (by September 30th) or even more frequently in case public pharmaceutical spending overruns. More specifically Law n.326 defines, among others, the following objectives for AIFA:

- 1) monitor public pharmaceutical consumption and expenditure (drugs dispensed by community and hospital pharmacies)
- 2) revise and update the positive list of pharmaceuticals on the basis of costs and effectiveness in order to ensure that the planned annual budget is respected
- 3) analyse costs and clinical effects of new drug;
- 4) allow inclusion of a new drug that doesn't provide additional therapeutic advantages in the positive list only if its price is equal or lower of the lowest price in its homogenous category (see above).

The NPF 2005 in comparison to the previous version is characterized by:

- 1) a higher number of active principles reimbursed, without exclusion of those previously included in NPF: additional 43 patented drugs were included for a total of 723 molecules (4474 packages)
- 2) a higher number of generics (15 new molecules included)
- 3) a selective price reduction of drugs deemed responsible of the budget overrun (it applied to over 50 active principles in 21 homogenous therapeutic categories).

The criteria used and methods applied to revise the NPF are explicitly stated in a document published by AIFA. The document is available to public.

In summary, the NPF 2005 is basically a list of pharmaceuticals, itemised without classification by levels, chapters or sub-chapters. Information available for each drug include: commercial name, package description, producer, active principle and price.

It was mentioned above that, even though the list of reimbursed drugs is defined at central level, their availability differs across regions due to different co-payment mechanisms adopted (Table 5). Furthermore, regions with co-payment mechanism differ greatly in exemption criteria adopted: clinical variables, income level, age..ecc.

Finally, for some drugs included in the positive list special limitations apply. Those limitations are defined in the AIFA Notes: a set of compulsory guidelines restricting the reimbursability of drug to specific diseases or patients' conditions (see above). The latest version of AIFA Notes was approved in November 2004. Various actors were included in decision making process concerning the definition of these Notes: doctors, pharmacists, producers, patients. The current guidelines include 41 notes with major ones referring to lipid-lowering agents, anti-ulcer drugs, injective antibiotics and non steroid anti-inflammatory drugs.

Table 5. Cost sharing on pharmaceuticals in Italian regions

Region	Flat rate (Euro)
Piemonte	2€ per package/ max 4€ per prescription
Aosta	No copayment
Lombardia	2€ per package/ max 4€ per prescription
Bolzano	2€ per package/ max 4€ per prescription
Trento	No copayment
Veneto	2€ per package/ max 4€ per prescription
Friuli	No copayment
Liguria	2€ per package/ max 4€ per prescription
Emilia Romagna	No copayment
Toscana	No copayment
Umbria	No copayment
Marche	No copayment
Lazio	1€ per packages over 5€
Abruzzo	2€ per package/ max 4€ per prescription
Molise	1€ per packages over 5€; 0,50€ for generics; max 3€ per prescription
Campania	No copayment
Puglia	2 € per package, max 5,5€ per prescription
Basilicata	No copayment
Calabria	1€ per package
Sicilia	2€ per package/ max 4€ per prescription
Sardegna	No copayment

E) Ministry Decree n. 332 / 1999 : " Prosthetic care services available in NHS. Provision modalities and tariffs"

Therapeutic appliances (prosthesis, orthopaedic appliances, hearing aids, medico-technical devices, wheelchairs and other medical durables) included in national health basket are defined in the decree approved by Ministry of Health on August 27th 1999. The main purpose of the decree was to define the reimbursement tariffs for appliances provided under NHS coverage. The document hasn't been updated from its approval, even though its revision is foreseen every three years. At present, an update of this benefit catalogue is included among primary objectives of the recently established National Health Basket Commission (see above).

The decree described defines the positive list of goods (organized in three separate lists) and the procedures that must be followed in order to provide them under public coverage.

Art. 2 of the decree further defines the categories of beneficiaries. It is also explicitly stated that, in particular cases of severe disability, local health authorities may authorize the provision of appliances not defined by the decree according to specific criteria set by the Ministry of Health (patient clinical conditions, specific procedures to be followed, and type of appliance).

The three catalogues are defined as follows:

- l) list n.1 includes all technical appliances (prosthesis, orthosis, technical aids) produced ad hoc or in series for which specialist prescription is required and for which the implant must be performed by a trained technician ("orthopaedic technician")

In the list n.1 goods are classified according to European classification ISO 9999 (European act EN ISO 9999). The classes included are:

- a) Curative and training appliances
- b) Prosthesis and Orthosis
- c) Aids for self care and protection
- d) Mobility aids
- e) Aids for home care
- f) Adaptations for home and work environment
- g) Aids for communication and signaling
- h) Aids for handling objects
- i) Environmental and car adaptations
- j) Aids for leisure time activities

List n.2 contains appliances (technical aids) produced in series whose provision doesn't require trained technician's intervention. More specifically, this list refers to particular technical aids in different classes defined above. For example:

- mobility aids: stamps, tripods, deambulatori, bicycles, wheelchairs..ecc
- aids for self care and protection: evacuation aids, catheters, urin absorbents
- home adaptation aids: beds with absorbing materials
- aids for communication: hearing aids, appliances for writing, telephones..ecc.

List n.3 contains goods that are directly purchased by local health authorities and provided to patients:

- respiratory curative aids: ventilators, oxygen therapy appliances, inhalators
- kits for injections
- aids for eating and drinking

In summary, appliances included in the three lists are categorized according to the ISO classification described above. Goods included in each class are listed as items without specific limitations to particular clinical conditions (over 200 pages of goods). For each item detailed description is provided together with classification codes.

The final decision about the general structure of the catalogue is made by Ministry of Health, following the agreement reached between the State and the Regions. Thus, the Permanent Conference on relations between the State and Regions is to be considered the main actor for priority settings regarding health care benefits. In the particular case of prosthetic care, the criteria used for defining the positive list are not explicitly stated.

Currently in Italy there is no HTA institution that offers support to decision makers. The 2003 Financial Law established the Commission for medical appliances (CUD- Commissione unica per i dispositivi medici) whose main objectives are to regularly update the positive list of appliances on the basis of scientific and economic criteria. Until today, however, the Commission has not produce any significant results.

F) National Contract for Primary Care services

It was mentioned above that National Contract for General Practitioners represents the fundamental benefit catalogues for primary care services in Italy. As to relative decision making process, the document is shaped and adopted through negotiations between the state, the regions and trade unions of primary care physicians and paediatricians. Following the agreement the document is then formally approved as a Presidential Decree (Decreto del Presidente della Repubblica- DPR)

The new National Contract adopted on February 28th is structured in two parts. The first part refers to "General contextualization", it has 11 articles that refer to issues like: general objectives of the national level of negotiations, duties and obligation of the negotiations at regional levels, role and participation of trade unions, funding arrangements.

The second part describes in more detail the rights and obligations of general practitioners across the national territory. This part is organized in 5 chapters according to area of care:

1. General principles (19 articles)
2. Primary Care (28 articles)
3. Continuous Care (11 articles)
4. Community care services (16 articles)
5. Emergency territory services (9 articles)

The main issues discussed across these chapters include regulations on working hours, representation by trade unions, organizational arrangements (group vs. individual practice), funding mechanisms, regulation of dual practice, etc.

In the chapter on Primary Care, article 45 defines duties and obligation of general practitioners across national territory.

Guaranteed services are described broadly as:

- a) all necessary services for acute and chronic disease management in line with best practice indications and in agreement with a patient
- b) patient management within programmed and integrative domiciliary care coordinated with providers of specialist and rehabilitative health care services, and if necessary, with providers of social care
- c) community care services defined at regional level

All necessary services are provided through ambulatory and domiciliary visits aimed at diagnosing and /or treating, by:

- 1) consulting with specialists and access to in-patient settings during various phases of hospitalization
- 2) holding and up-dating individual health records in electronic form
- 3) participating in various forms of group practices in the community
- 4) providing certifications for temporary incapacity to work, school readmissions, sport activity
- 5) multi- dimensional evaluation and necessary certifications for domiciliary care and residential nursing-homes admission
- 6) developing and spreading information about health life styles: getting to know national and regional health services; information on: blood and organ donations, transplantation, cost-sharing mechanisms adopted and relative exemptions; appropriate use of health care services
- 7) participating in preventive and curative immunization programs promoted at national or regional level
- 8) appropriate use of healthcare resources and respect of economic targets set by regions
- 9) additional services (Appendix D, see section 2)
- 10) provision of care in remote areas
- 11) occasional visits

Thus, a specific list of primary care service is not available in Italy. National Contract rather provides a general framework within which general practitioners are required to operate across the country.

The document is up-dated every two-three years at national level, while regional agreements may have different timelines.

G) Ministry of Health Guidelines on Rehabilitation Care

The Guidelines were approved by the Permanent Conference on State-Regions relations on May 7th 1998 and subsequently published in Official Law Journal on May 30th 1998.

The primary objective of the document is to define indications for organizing rehabilitative care networks and main criteria for the services available under uniform levels of care introduced by National Health Plan 1998. The general framework is outlined as integrated approach to health and social care services. The guidelines for rehabilitative care refer to WHO ICIDH classification (International Classification of Impairment, Disabilities and Handicap).

The document is organized in three parts addressing the following issues:

- 1) strategy of rehabilitative interventions/ services
- 2) phases and types of rehabilitative care and organization of providers
- 3) actions for implementation of guidelines across regions

In the first part, the main characteristics and objectives of rehabilitative care services are outlined with particular attention to distinguishing between "health" and "social" care services provided within rehabilitative programs.

Part two is the most extensive one of the document and it mainly addresses different settings of care where rehabilitative care services should be provided. The following settings are defined:

- hospital long term care
- ambulatories (hospital or community based) for functional recovery and re-education
- rehabilitative day and/or continuous care centres (outpatient)
- residential, i.e. nursing homes (RSA) (medium level of medical, nursing health care services available)
- residential and semi-residential health-social care centres

In all of these settings of rehabilitative care, the following functions are guaranteed:

- participation to primary prevention and health promotion programs
- diagnostic and curative care services aimed at minimizing secondary and tertiary complications responsible for long-term residual disability
- prescription, maintenance of prosthesis and orthotic appliances included in the national fee schedule and monitoring of their efficacy
- technical assistance for social and professional integration and correlated issues (architectonic barriers, certifications..ecc)

Furthermore, the document provides general guidelines on highly specialized centres of care explicitly stating that Regions are autonomous in defining specific contents of care as well as accreditation procedures for:

- 1) Spinal units
- 2) Units for severe cerebral and cranio-encephalic lesions/trauma
- 3) Units for severe disability in advanced stages
- 4) Units for rehabilitation of neuropsychological disorders

Finally, the last part of the document provides indications on how the regions should adopt and implement the national guidelines.

4. DISCUSSION

The issue of the definition of the basic package is embedded in the history of the Italian health care system. The Italian Constitution enacted after WWII explicitly introduced the right of health as a major social right of Italian citizens. In the period 1948-1978, according to this principles, beneficiaries of health protection gradually increased and the content of the benefit packages expanded under a fragmented system where compulsory social insurance for employees was coupled with programmes publicly funded by government institutions (at national and local level). As a result, in the late '70s almost 90% of Italians had a statutory coverage but without a clear national framework regulating the content of their protection. Before the introduction of the Italian NHS, numerous social insurance funds provided different benefit packages and providers (mainly run by institutions controlled by the government) operated under complex reimbursement systems; in this period both government owned providers and social insurance funds incurred large financial deficits.

In 1978, Italy approved a grand reform that resulted in the introduction of a National Health Service largely inspired by the British experience. Previous funding was channelled into a national fund to be redistributed to Regions and then to Local Health Units. A national right to health services under a government run system was explicitly introduced and LHUs, a territorial network of government owned organisations, were mandated to provide all services deemed necessary to protect health. These services included primary and specialist (in-patient and out-patient care), pharmaceutical care, public health and preventive medicine, environmental health services, veterinary care and occupational health. The 1978 reform, the most relevant in the area of social welfare of the Italian republic, was primarily focussed on social and geographical equity principles and implicitly assumed that the entire Italian health system would have been absorbed by the National Health Service. It also assumed an unconditional right to health services without a clear reference to limits to public coverage and to economic constraints. It stated that future legislation would have defined the list of services made available to citizen, but it was not mentioned according to which principles and criteria this list should have been created. Indeed, in its first 15 years of life the NHS worked without a clear framework on the benefits guaranteed by the NHS.

This lack of clarity have contributed to a weak government control over public expenditure as LHUs and regions constantly overran annual budgets; the unconditional right of health care was often used by public providers justify overspending; the argument was that overspending was necessary in order to meet the national right of health care. From one side, the national government tried to control expenditure setting tight financial limits, to the other Regions and LHUs found in the vagueness of public coverage the legal protection to overspend and to limit cost-containment interventions. This lack of accountability was facilitated by the institutional structure of the system. While the central government was the payer, regional and local politics, in charge for running the system, had strong incentives to expand health services provision to please their electoral bodies. As a by-product of this lack of regional and local financial accountability, the national government introduced national legislation to limit decision-making at regional and local level. By freezing employees turn-over and by setting tight limits on hospital capacity the central government tried to control local expenditure. However, this generated more rigidity in the system, complaints of violation of regional and local institutional autonomy and, paradoxically, a further deterioration of financial discipline at provider level.

In the period 1978-1992 a clear definition of the guarantees offered by the NHS was not in the political agenda. In principles, citizens were entitled to almost any health service as legislation did not clearly state that the extent of coverage had limits. In practice, however, limitations to the access of care were in place because of waiting lists or actual unavailability of services. De facto, traditional implicit rationing mechanisms were at work with substantial disparities across the country.

An overdue reform was approved in 1992, under unprecedented pressure to contain public expenditure to meet Maastricht criteria for joining the monetary union. The reform overtly introduced the idea of the benefit package and identified regions as the pivotal institutions in the health care sector. Regions were attributed new organisational powers and were made accountable to provide a nationally defined set of services under pre-determined resources. At least in theory, the new rules were clear: the national government mandates a benefit package and makes enough resources available to allow its provision; the regions are required to offer the package to its citizen. In practice, however, the implementation of the new system found

two main obstacles: a) the difficulties to operationally definite the benefit package; b) the introduction of a credible system to make regions accountable. As the first issue is concerned, it took time to make the concept of the benefit basket operational. Criteria to determine the minimum package were legislated in 1999 and an overall catalogue was released in 2001. As discussed earlier, relevant progresses have been made to clarify NHS coverage. Entitlements to services in particular areas (e.g. pharmaceuticals and, to a lesser extent, out-patient care) are now clearly defined and some services (e.g. dental and thermal care) are explicitly excluded. However, in the area of hospital care entitlements remain broad and general. The second major issue concerned how to make regions accountable to the new rules. This involves three major interrelated aspects a) the rules to set the overall financial budget made available to regions, b) the system to monitor that the national benefit package is actually provided and c) the penalty/rewards rules to make regions accountable.

The dominant interpretation of the present rules state that the government should concomitantly define the benefit package and the financial resources required to make it available. In practice, this means to set the resources to be made available and then to identify the entitlements. Possibly, this sequence is logically feasible but in practice it would require to vary the content of the benefit basket regularly and depending on public expenditure policy. With the exclusion of pharmaceutical policy, decisions about funding and the benefit packages are not so strongly linked and the information system is so developed to make it possible to re-adjust entitlements according to expenditure policy. In practice, decision making processes follow two different paths and are only partly reconciled. It is worth mentioning that such reconciliation is mandated for pharmaceutical care. For this type of care, the National Agency for Pharmaceuticals (AIFA) is mandated to reduce expected increases in expenditure (e.g. through exclusion of products from the positive list) in case there is a clear expectation of overrunning a predetermined cap.

For pharmaceutical care the monitoring system allow to collect evidence on expenditure and utilization month by month. In addition, policy measures have a rapid impact as pharmaceutical products are purchased from external providers. For the remaining areas of care measuring costs and activities is more difficult and policy interventions need more time to affect expenditure. As presented earlier, important steps have made to implement an adequate system to monitor both costs and activities. However, it looks that the present system is not mature enough to know whether regions are actually providing the entitlements mandated at national level. Nor the way requirements are formulated can easily generate "legal rights" to be check by courts.

Finally, it is unclear how to make regions fully accountable to the provision of the minimum package. Regions still have limited fiscal powers so to make difficult a substantial revenue collection in case the minimum package is not provided due to inefficiencies. In addition, it is likely that less efficient regions are also those with lower regional income and, consequently, with lesser fiscal capacity. In theory, the national government can destitute regional governments in case of serious deficiencies. However, this has never occurred so far and, at present, looks a very unlikely event.

As in other countries, in Italy a clear definition of the benefits provided by the statutory system is thought to be beneficial for several reasons; it may contribute to a better allocation of resources, it could help reassuring patients about their rights and responsibilities and it can facilitate the development of supplementary insurance. Nevertheless, the definition of a benefit package in Italy is a crucial issue in connection with the relations between the central government and the regions. The definition of the guarantees to be offered at national level is seen as the means to keep management and policy powers at regional level while maintaining national guarantees. In this sense, the basic package is primarily a policy devise to keep regions accountable to national standards.

A new constitutional reform aimed at a redistribution of powers from the State to the regions is presently under parliamentary discussion. It specifies that powers on health matters are in the exclusive hands of regions, provided that national principles are respected. If this reform is approved, the importance of the basic package would gain even more importance. It will be the main policy tool in the hands of the state to maintain a national uniform right to health care. Therefore, we foresee the need of substantial investments to further specify the content of the package and, more importantly, to develop adequate monitoring systems and accountability procedures. In our opinion, two issues are particularly critical in this respect. First, the reconciliation between benefits and resources to make them available requires an adequate governance system. At present

Italy does not have a higher chamber (even it may be introduced in the Constitution reform under discussion) where regions are represented and where negotiations between them and the state find an appropriate institutional framework. At present, the devolution process does not find adequate rules to govern negotiations and conflicts. The risk of institutional conflicts, endless negotiations, legal disputes and lack of coordination is very real and, so far, would mainly affect the health care sector. It should be clear that without adequate governance mechanisms, conflicts between the two tiers of government (regions versus the state) and between the regions may result in further acceleration of a fragmentation of the National Health Service with likely differentiations between regional health care systems. The second issue concerns an adequate infrastructure to sustain the national government as guarantor of health care rights. Without an appropriate information system, new competences and appropriate powers the national tier cannot ensure its guarantor role. Again, these elements are strictly connected with the issue discussed in this document. To implement effective national guarantees the national government needs to develop the benefit package, to implement an effective monitoring system and to design appropriate rules to force regions to act adequately. On the other hand, these conditions are also needed to ensure that resources available to the regions are compatible with the cost of the provision of services included in the benefit package.

More detailed reflections can be made about the criteria adopted in Italy to build the benefit package, the features the decision processes and the issue of costing. Effectiveness (in most cases efficacy) , as proven by scientific evidence, is the dominant criterion stated and used in the definition of the package. This is the main criterion adopted for the inclusion of pharmaceuticals in the positive list and for the exclusion of specific rehabilitative and thermal services. A major issue is how to extend the use of the effectiveness criterion to diagnostic tests, surgical procedures and medical devices. At present, the Italian NHS has not greatly invested in technology assessment activities and the introduction of new technologies is not under control of national government. Need criteria have been also used; ailments for minor conditions (tough, sore throat, minor headache), aesthetic surgery, ritual circumcision are excluded on the basis of various interpretations of the need criteria. Also, it can be stated that dental care was excluded on this ground, even if this has never officially stated. Cost-effectiveness criteria are explicitly stated for the inclusion in the positive list of pharmaceuticals but it remains unclear the role of cost-effectiveness studies in the actual decisions about reimbursement and pricing. In the meanwhile, it is clear that cost minimization principles are used when clinical alternatives with the same effectiveness profiles are available. As mentioned above, appropriateness criteria play a relevant role in the Italian case. They are often mentioned in official documents and the release of a list of DRGs deemed at high risk of inappropriateness has contributed to promote regional awareness on this issue. In general, both clinical and organizational appropriateness are promoted. As the former require that treatments and procedures are applied only to patients with particular clinical conditions (e.g. the notes on restrictions on the use of statins), the latter try to assure the patients are treated in the most adequate (and often cheapest) setting. Overall, the use of appropriateness criteria suggest that benefit catalogues should be lists of services for particular clinical conditions rather than simple lists of services.

As presented above, different decision making processes are in place. Although the Dpcm has unified most of them, pharmaceutical care and primary care are still managed differently. The positive list is managed by a central agency according to a consolidated procedures, while primary care services result from the national contracts between government and trade unions. For the remaining services, the benefit package is managed through a negotiation between the State and the regions. For these services, decision-making rules are still under development. In general, as stated above, the crucial role played by the benefit package still need adequate institutional arrangements and operational procedures.

Recently, the national government has introduced a monitoring system of costs incurred to provide the benefit package. It mainly consists in the collection of information on costs attributable to the broad categories of services defined in the decree. In theory the main objective of the system is to monitor whether resources made available suffice to provide the basic package and are actually used by regions. In practice, however, the system provide a description of how resources are allocated by regions between the broad categories of care. At present, data collected can only suggest how resources are allocate by regions and whether this allocation is consistent with direction given by the national government. They are also used to construct simple indicators (per capita pharmaceutical expenditure, cost per admission and cost per hospital bed) so to make comparison between the regions. As a matter of fact, an overall monitoring system of the benefit package is still not fully developed and the real objective of the present collection of cost data is unclear. An affective system to make regions

accountable to the national government for the provision of the benefit package should mainly focus on services provided rather than costs. Collection of cost data is very important but should mainly focussed on getting evidence on resources needed to provide the package and thus should be strictly related to financial forecasts and planning.

Figure 1. Decision making on benefits in Italy

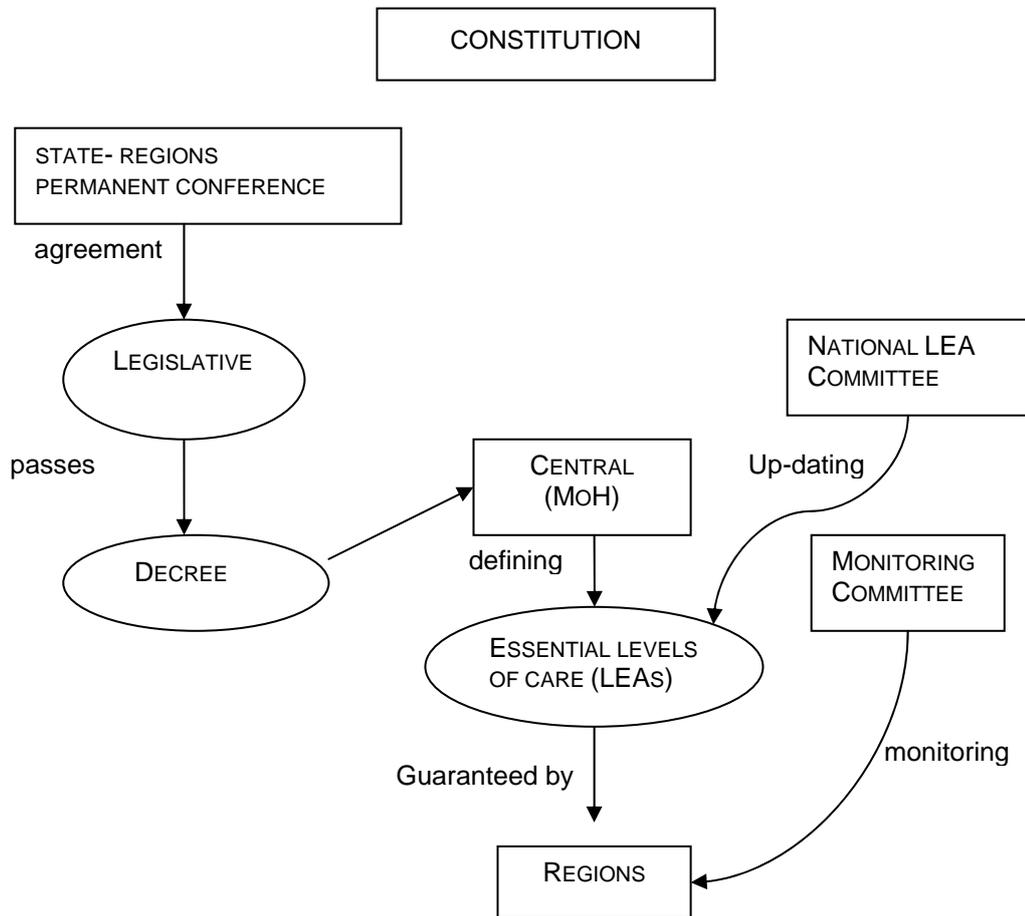


Figure 2. Decision making on pharmaceuticals in Italy (covered by NHS)

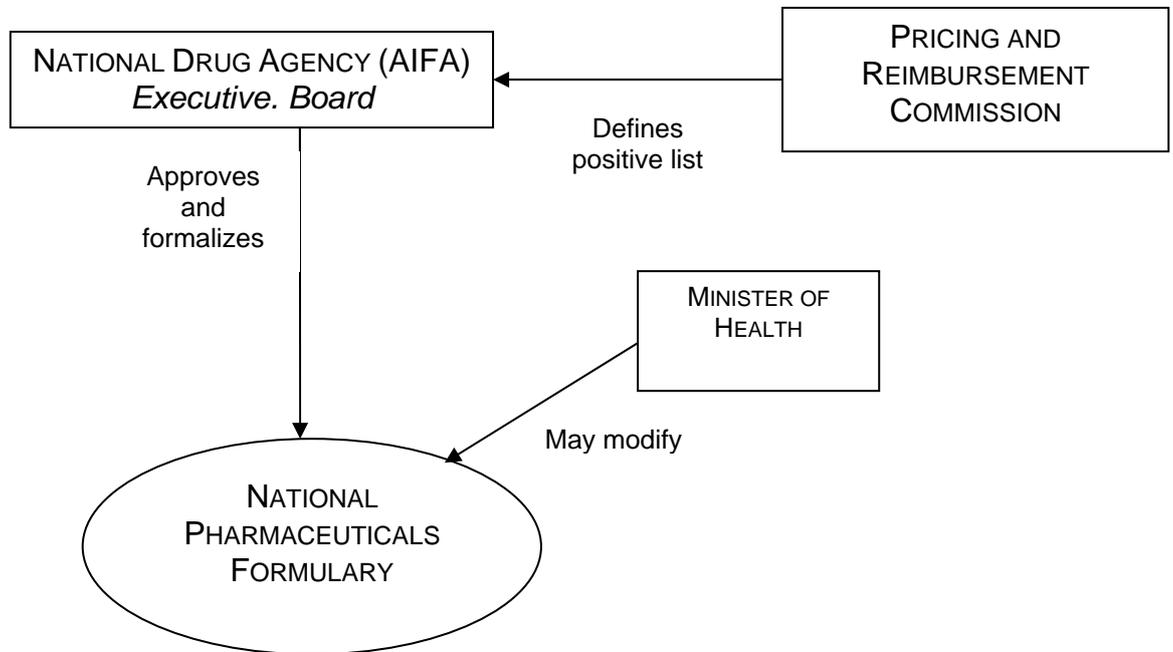


Figure 3. DPCM November 29th 2001: Definition of national standards of care (LEAs)

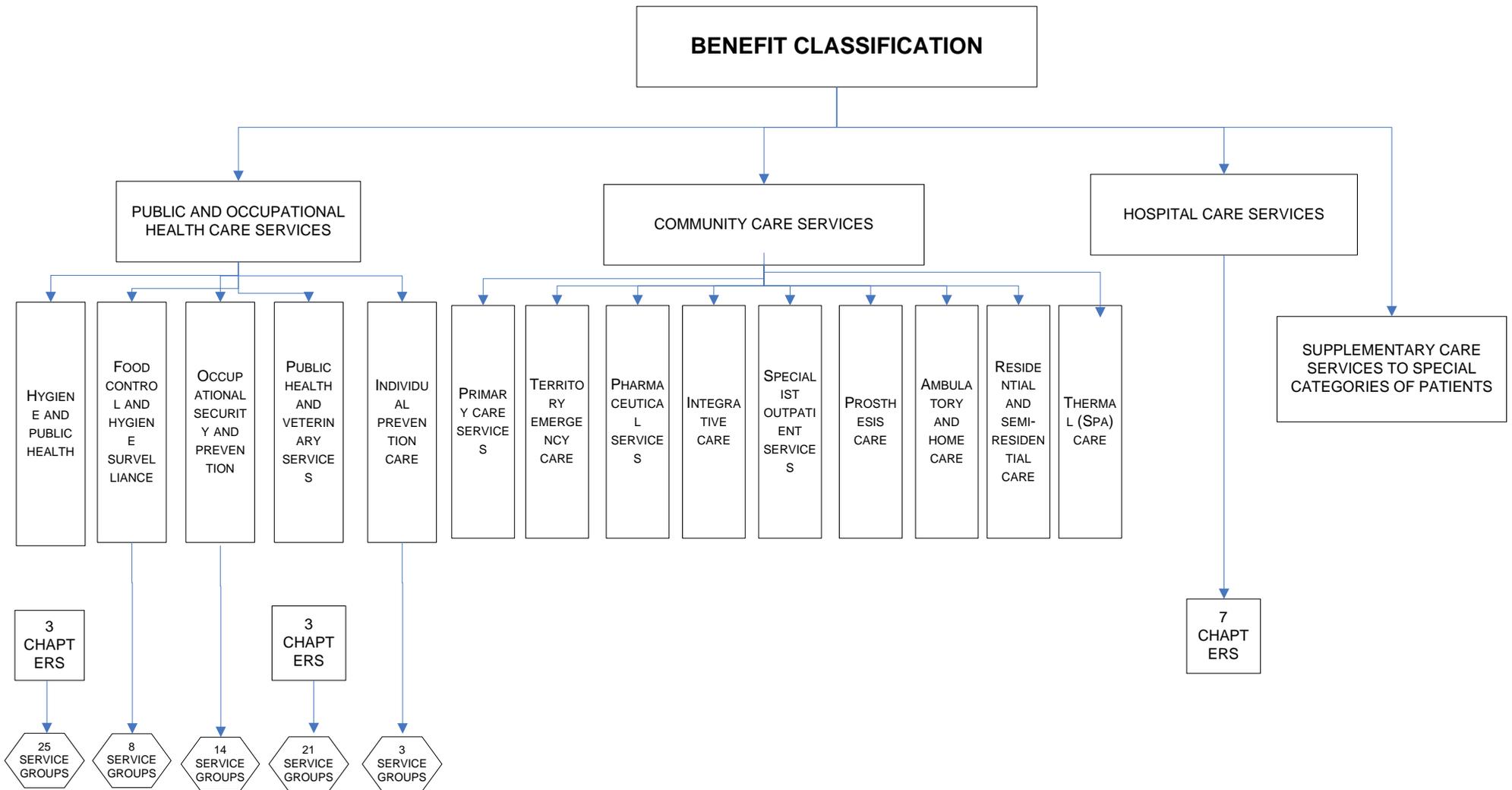


Figure 4. Assigning of DRG in Italian system

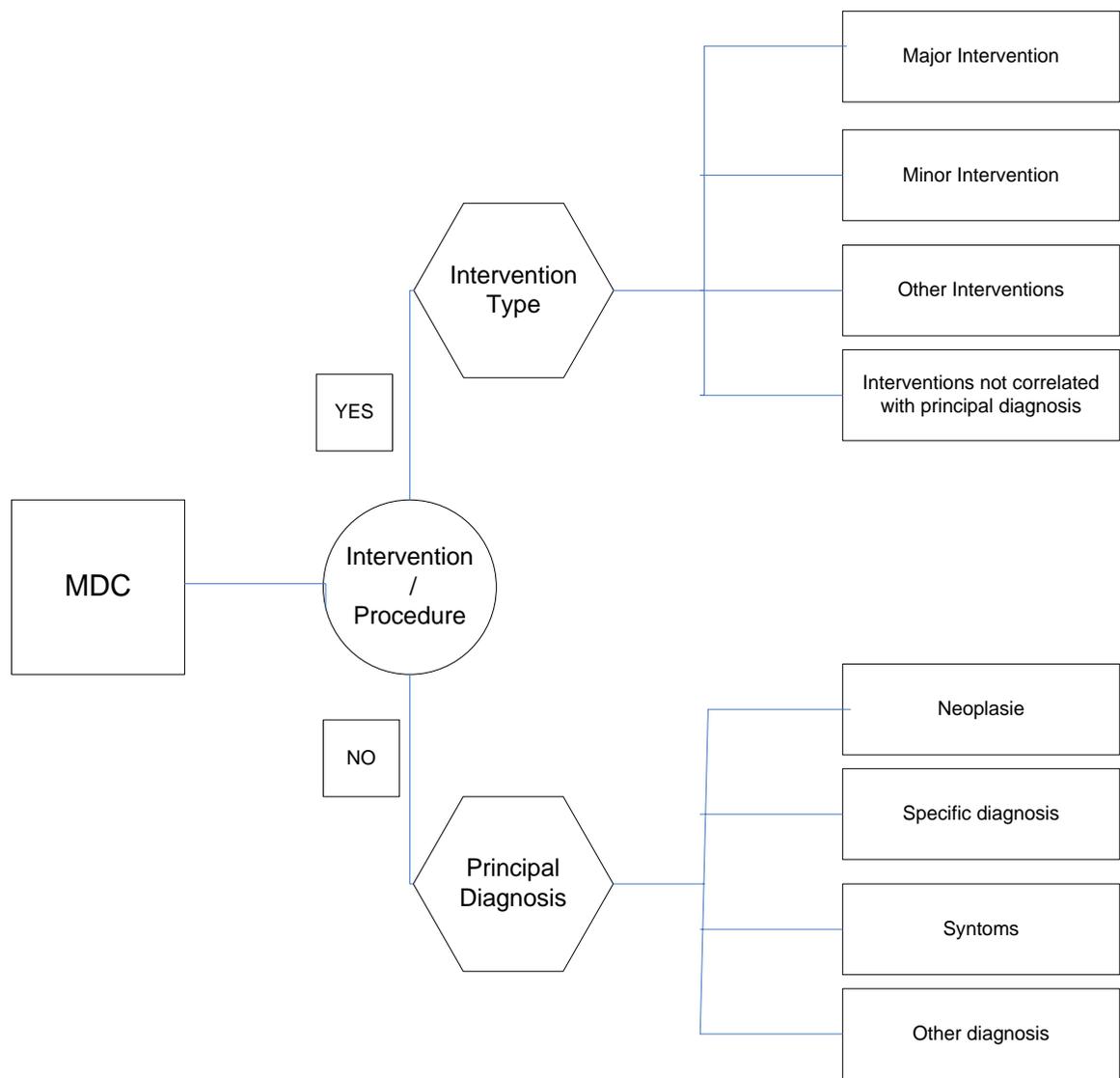


Figure 5. DM July 22nd 1996: specialist out-patient services

