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Ane Auraaen, Rie Fujisawa, Grégoire de Lagasnerie, Valérie Paris

How OECD health systems define the range of good and services to be financed collectively

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HOW OECD HEALTH SYSTEMS DEFINE THE RANGE OF GOODS AND SERVICES TO BE FINANCED COLLECTIVELY

Ane Auraaen, Rie Fujisawa, Grégoire de Lagasnerie, Valérie Paris*

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ABSTRACT

Universal health coverage has been achieved in nearly all OECD countries, providing the population with access to a defined range of goods and services. This paper provides detailed descriptions of how countries delineate the range of benefits covered, including the role of health technology assessment and specific criteria to inform the decision-making process. Further, the paper examines the composition of assessment/appraisal and decision-making bodies across the different OECD health systems, highlighting the role of patients and public as well as transparency of decision-making processes. While the process of including new technologies to the range of benefits covered is structured and relies on a well-defined set of criteria, dynamic adjustments of the range of benefits covered are less structured. The paper then looks at the boundaries of health care coverage and presents a set of services for which coverage varies greatly across the OECD countries.

RÉSUMÉ

La quasi-totalité des pays de l'OCDE offrent à présent une couverture maladie universelle, donnant accès à leur population à un panier défini de biens et services de santé. Ce document décrit en détail la manière dont les pays définissent les contours de ce panier de soins, notamment le rôle de l'évaluation des technologies et des critères utilisés pour éclairer la prise de décision. Ce document examine également la composition des instances responsables d'évaluer les technologies et de prendre les décisions en matière de couverture, mettant en évidence le rôle des patients ou du public en général et la transparence du processus de décision. Alors que le processus visant à inclure de nouvelles technologies dans le panier de soins est en général très structuré, les processus d'ajustements dynamiques du panier de soins sont moins bien définis. Ce document analyse enfin les contours du panier de biens et services couverts dans les pays de l'OCDE en analysant un ensemble de biens et services de santé, dont la couverture varie largement d'un pays à l'autre.

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HOW OECD HEALTH SYSTEMS DEFINE THE RANGE OF GOODS AND SERVICES TO BE FINANCED COLLECTIVELY

1. Introduction and context

1. All OECD countries have implemented or are approaching universal health coverage. There is now a wide consensus that this is the most effective way to create more inclusive societies, by assuring citizens' access to the health services they need regardless of their ability to pay. By contrast, a significant number of attributes of "universal health coverage" are not consensual at all and countries have chosen different options to organise and finance health coverage (Paris et al., forthcoming), and to delineate the range of benefits covered through various tools and processes, although some cross-country trends are observed.

2. New advances in medical technologies are expanding the range of treatment options, devices, and medicines available to treat patients. At the same time, public expectations regarding which medical goods and services will be available to address their medical needs are also growing. With growing health care expenditure and public budgets under strains, concerns about the long-term financial sustainability of health systems have led policy makers in many OECD countries to seek ways to rationalise the boundaries of "collective financing".

3. Several studies already analysed how some countries define the range of benefits covered by public health systems and/or compulsory contributory health insurance schemes. The most comprehensive ones analysed health benefit baskets in nine European countries (Schreyögg et al., 2005), decision-making processes for specialist services in nine countries (Stolk et al., 2008), decision-making processes for drug reimbursement in five countries (Le Polain et al., 2010), and the development of health benefit plans in South American countries (Giedion, 2014).

4. Taking stock of these earlier studies, this paper provides an analysis of the tools, processes, criteria and strategies used by countries to define and update the range of benefits covered. The analysis is undertaken based on the information received from 27 OECD countries who responded to the OECD Survey on Health Benefit Basket conducted in 2014¹ and complementary information collected through the 2012 OECD Health System Characteristics Survey, other OECD studies and available literature. The paper also reviews the coverage of some categories of services which are not homogenously covered in OECD countries, such as OTC medicines, dental care, vision products, and complementary and alternative medicines based on information collected through above-mentioned OECD surveys.

5. This paper first describes how OECD countries delineate the range of benefits covered (section 2) and the institutional processes that govern coverage decisions (section 3). Then, it describes methods and criteria used in the decision-making process for inclusion of new health technologies² in the range of benefits covered and collectively funded (section 4), as well as strategies used to adjust the

¹ Austria, Estonia, Germany, Ireland, Italy, Mexico and New Zealand did not respond to this survey.

² In this report, "technology" is employed as a generic term including new medical procedures, new medicines and new medical devices.

content of the benefit basket over time (section 5). Section 6 highlights cross-country differences in the coverage of a range of health interventions that are not consistently covered across OECD countries, and the last section discusses trade-offs and future challenges in relation to adjusting the range of benefits covered.

2. How do OECD countries delineate the range of benefits covered?

6. Countries use different approaches to delineate the range of benefits covered and funded collectively (section 2.1), partly influenced by the organisation of health coverage (sections 2.2 and 2.3). However, overall, positive lists are the norm for pharmaceuticals, although not for medical procedures and devices (section 2.4). Different approaches in delineating health care coverage have advantages and drawbacks (section 2.5).

2.1. The range of benefits covered can be defined explicitly or implicitly, positively or negatively

7. While OECD countries have organised health care coverage in very different ways, most of them have defined, at a central level, a range of benefits covered by residence-based public health systems schemes or compulsory health insurance (Box 1). This is done:

- *Explicitly*, through itemised lists of goods or services covered (e.g. a list of reimbursed medicines or surgical procedures), or *implicitly*, by reference to a broad category of services (e.g. primary care services);
- *Positively*, by referring to what is covered, or *negatively*, assuming that everything which is not explicitly excluded from coverage (broad categories or specific items) is covered.

8. Countries most often use a mix of these instruments to define the range of benefits covered (Table 1) but some trends are observed (sections 2.2-2.4).

Main source of basic health care coverage	Country	Positive list, central level	Negative list, central level	Hadividual payers positive lists	Individual payers negative lists	Providers' positive lists	Benefit basket not defined	Positive list, central level	Negative list, central level	positive lists	Individual payers	Providers' positive lists	Benefit basket not defined
	Australia	•	0	•	0	0	0	•	0	0	0	0	0
e e	Canada	0	0	•	•	õ	0	0	0	ě	0	0	0
ag	Denmark	•	0	0	0	0	0	0	0	0	0	0	•
Sve	Finland	•	0	0	0	0	0	0	0	0	0	0	•
ŭ L	Iceland	•	•	0	0	•	•	0	0	0	0	0	0
salt	Ireland	•	0	0	0	0	0	0	0	0	0	0	•
dge	Italy	•	•	0	0	0	0	•	•	0	0	0	0
Residence-based gealth coverage	New Zealand	•	0	0	0	0	0	0	0	0	0	•	•
-a	Norway	•	0	0	0	0	0	0	0	0	0	0	•
DC .	Portugal	•	0	0	0	0	0	0	0	0	0	0	•
side	Spain	•	•	0	0	0	0	•	•	•	0	0	0
Ree	Sweden	•	0	0	0	0	0	0	0	0	0	0	•
	UK (England)	0	•	0	0	•	0	0	0	0	0	•	0
	Estonia	•	0	0	0	0	0	•	0	0	0	0	0
a at a	Hungary	•	0	0	0	0	0	0	•	0	0	0	0
e pe	Korea	•	0	0	0	0	0	•	•	0	0	0	0
ing	Greece	•	0	0	0	0	0	•	0	0	0	0	0
out e, s	Luxembourg	•	0	0	0	0	0	•	0	0	0	0	0
Contributory health coverage, single payer	Poland	•	0	0	0	0	0	•	0	0	0	0	0
Con	Slovenia	•	•	0	0	0	0	•	•	0	0	0	0
	Turkey	•	0	0	0	0	0	•	0	0	0	0	0
≥. <u></u>	Austria	•	0	0	0	0	0	•	0	0	0	0	0
Contributory coverage, multiple insurers with automatic affiliation	Belgium	•	0	0	0	0	0	•	0	0	0	0	0
trib tor a filia	France	•	0	0	0	0	0	•	0	0	0	0	0
aff ar is a could	Japan	•	0	0	0	0	0	•	0	0	0	0	0
<u> </u>	Mexico	٠	0	0	0	0	•	0	0	•	0	0	•
ge'	Chile	•	0	•	0	0	0	•	0	•	0	0	0
Contributory coverage, choice of insurer	Czech Rep.	•	0	0	0	0	0	•	•	0	0	0	0
ıtributory covera choice of insurer	Germany	0	0	0	0	0	•	0	0	0	0	0	•
of it.	Israel	•	0	0	0	0	0	•	0	0	0	0	0
ce i	Netherlands	•	0	0	0	0	0	0	0	0	0	0	0
h r is	Slovak Republic	•	0	0	0	0	0	•	0	0	0	0	0
Log of the second secon	Switzerland	•	0	0	0	0	0	0	•	0	0	0	0
0	United States	0	0	•	•	0	0	0	0	•	•	0	0

Table 1. How do countries define the range of benefits covered?

Source: OECD Health Systems Characteristics Survey 2012 and authors estimates. Note: Positive list only applies to pharmaceuticals use in outpatient care in the Netherlands.

Box 1. Definitions

In this report, the "range of benefits covered" refers to *benefits covered by residence-based public systems or compulsory contributory insurance schemes,* as defined in the new system of health accounts (OECD-WHO-Eurostat System of Health Accounts, 2011). In this definition, *benefits* refer to preventive, curative, or rehabilitative services and to medical goods, whose coverage may be restricted to specific indications or targeted population. *Coverage* may be full or partial (with user charges).

Previous studies have used the terms "benefit basket/package" (for European countries) or "health benefit plan" (for South American countries). While the former referred to "publicly funded benefits", without prejudice about the way this "basket" was defined (implicitly or explicitly, through positive or negative lists), the second referred to "explicit guarantees [...] financed with public resources". In Chile, for instance, the Health benefit plan establishes a list of priority interventions, to which insurers are required to guarantee timely access. Interventions which are not listed have a lower level of priority, without being excluded from coverage (Schreyögg J. et al., 2005; see Giedion at al., 2014).

The use of the terminology "health benefits basket (or package or plan)" is not consensual. In countries where the range of benefits covered is not explicitly defined or in countries where benefits entitlements vary across population groups, it does not seem very appropriate indeed. However, for the sake of simplification, this report uses alternatively as synonyms the terms "range of benefits covered", and "health benefit basket (or package)".

2.2. Countries with residence-based health systems tend to define the range of medical services covered in very broad terms

9. A majority of countries with residence-based health systems do not explicitly define the range of health care services covered through itemised lists (Table 1). This is the case in particular of Nordic countries (e.g. Denmark, Finland, Norway and Sweden), but also of Ireland and Portugal. In Finland, for instance, municipalities and hospital districts have significant autonomy in defining and shaping the services they provide, which leads to variations in the range of services available across municipalities. In Sweden, there is no explicit itemised list of services, but there are some broad definitions as to what does and does not fall within the domain of health care, and some general guidelines also exist with regards to the priorities of the health care sector.

10. In countries with decentralised systems, such as Canada, Italy or Spain, a minimum benefit package is defined at the central level (Box 2). Sub-levels of governments have to provide this minimum to their residents and are allowed to expand at their own expenses. In the United Kingdom (England), the range of benefits covered is only defined in very broad terms, but local clinical commissioning groups can draw up positive lists.

Box 2. Approaches taken to delineate the range of health care services in decentralised residence-based systems

In Canada, the Canada Health Act (CHA) requires each province and territory to operate a public health care insurance plan that provides universal pre-paid coverage for "medically necessary hospital and physician services". Governments of provinces and territories define further the range of covered services, most often through fee schedules, which function as a positive list of benefits (OECD, 2012).

Italy and Spain use both positive and negative lists to define the range of medical services covered in their decentralised national health systems. In Italy, a positive list (livelli essenziali di assistenza – or LEAs) includes all services that the Italian NHS (SSN) is required to provide uniformly in all regions. It covers outpatient specialist care, clinical laboratory tests, diagnostic imaging and rehabilitation procedures. A short negative list includes three categories of ambulatory and hospital services that should not be provided within the national system, i.e.: services proven to be clinically ineffective or beyond the responsibility of SSN (e.g. cosmetic surgery, except for malformation and injury, ritual circumcision, non-conventional medicine, medical examinations and vaccinations for employment and vacation purposes, and a few types of physiotherapy); diagnostic and therapeutic ambulatory services included only on case-by-case basis (e.g. bone density testing, laser eye surgery and orthodontic services); and potentially inappropriate hospital admissions (such as carpal tunnel release, cataract surgery and hypertension care) for which regions are required to provide treatment in other settings such as day cases and ambulatory care (Lo Scalzo et al, 2009). In Spain, the national positive list includes a number of services including psychoanalysis/hypnosis, spa treatment and plastic surgery not related to accidents, disease or congenital malformation (Garcia-Armesto et al, 2010).

In the United Kingdom, the range of benefits covered is not clearly defined but providers can establish positive lists. In England, the National Institute for Health and Clinical Excellence (NICE) systematically assesses the risks and effectiveness of interventional procedures (those involving incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy) in order to provide guidance for routine use in the NHS. Local clinical commissioning groups update their positive lists based on this guidance.

2.3. Countries with health insurance systems most often use positive lists to define the range of services covered

11. Countries with health insurance systems have at least two good reasons to draw positive lists of covered services: the first one is that they often operate as open-ended systems with loose budget constraints, which therefore requires a collective agreement on what should be reimbursed or paid for.

Second, health insurance systems often pay providers (especially doctors) on a fee-for-service basis, which requires the definition of a fee schedule. Among OECD countries, countries with health insurance systems all define positive lists of covered medical services, except Germany, Hungary, Mexico, Netherlands (only pharmaceuticals used in outpatient care), Switzerland, and the United States.

12. Countries with *single-payer health insurance systems* all define the range of covered services through positive lists, except for procedures in Hungary. This feature is quite recent in Greece, where different insurance schemes were merged in 2011 into a single scheme - called EOPYY (National Organization for Health Care Services Provision). Korea and Slovenia use both positive and negative lists, in order to specify limitations or restrictions in use of certain interventions. In Korea, the negative list includes health care goods and services which are not required in the treatment of specific diseases, and in Slovenia, the negative list indicates limitations and restrictions for the coverage of services and benefits where relevant.

13. Countries with *multiple health insurers and automatic affiliation* (i.e. no choice of insurer) have generally defined a single and uniform health benefit package (e.g. Belgium, France, and Japan). In Austria, however, the positive list only defines a "minimum benefit package" and individual insurers are allowed to differentiate the benefit package beyond this minimum coverage (Hofmarcher, 2013).

14. Countries with *multiple competing health insurers* most often define benefits covered at the national level through positive lists (e.g. Israel, and the Slovak Republic). The Czech Republic combines a positive and a negative list for procedures. Switzerland defines the range of services covered in broad terms³ but draws up a negative list of services not covered or only covered in certain circumstances.

15. However, in countries with multiple insurers in North and South American countries (e.g. Chile, Mexico and the United States), the range of benefits covered is defined at the insurer level and varies across insurance schemes (Box 3).

Box 3. Multiple insurers and different benefit coverage in North and South American countries

In Chile, the range of benefits covered varies across insurance schemes. Positive lists for both pharmaceuticals and medical procedures are available at individual insurer's level for employment-based insurance (ISAPRE) while the benefit basket for the Fondo Nacional de Salud (FONASA), for those not covered by an ISAPRE, is defined by positive lists set at the national level. A set of explicit guarantee is defined for all plans, requiring them to give priority access to a range of benefits (Giedion et al., 2014).

In Mexico, employees of the formal sector are automatically affiliated to the relevant social health insurance scheme while other residents can –but are not obliged to- enroll with Seguro Popular or to private health insurance. Employment-based insurance schemes do not define the range of health benefits covered. On the other hand, Seguro Popular explicitly defines the boundary of health care funded collectively and covers all basic primary health procedures, many hospital discharges and pharmaceuticals listed in the Universal Catalogue of Health Services (CAUSES) which is set at the central level.

In the United States, most individuals receive health insurance from their employer, and the range of benefit covered varies by insurance provider. Individual insurers draw positive and negative lists of medical services covered at their discretion. The Affordable Care Act (ACA) requires all insurance plans to cover a range of preventive services without user charges (e.g. immunisation vaccines, obesity screening and counselling, tobacco use screening, etc). The ACA also requires private health insurance plans sold on state health insurance exchanges and to all individual and small group plans sold outside the exchanges to cover a set of "essential health benefits" from 2014 onwards (Bagley

³ There is no standard definition of what is medically necessary and it is often left to physicians' discretion. In Switzerland, the legal system is built on the assumption that treatment and examination by doctors is reimbursed. Furthermore, admission to a general hospital ward and medical rehabilitation, for example, are reimbursed (Stolk, 2008).

and Levy, 2014). After hesitations about the process to define this set of essential benefits and a consultation of the Institute of Medicines for advice, it was decided that this set of essential benefit should be defined at the state level, by reference to a "benchmark plan". The benchmark plan can be selected among the three largest insurance plans in the state's small-group market and three largest plans available to state employees.

2.4. All OECD countries but four use centrally-established positive lists to define which medicines are covered

16. Regardless of differences in the organisation of health care coverage, almost all OECD countries define positive lists at the central level for pharmaceutical coverage. Positive lists are drawn for both medicines used in inpatient and outpatient care (e.g. Austria, Belgium and France) or only for medicines used in outpatient care, with hospitals establishing their own formularies (e.g. Finland). A few countries use simultaneously positive and negative lists (e.g. Iceland, Italy and Spain). Spain, for instance, draws a negative list of pharmaceuticals of low therapeutic value, referring to drugs which have not proven to have an adequate incremental cost–effectiveness ratio.

17. However, four OECD countries do not use centrally-established positive lists to define which medicines are covered by collective funding (Table 1). They include Canada and the United States, where a majority of the population obtain coverage for medicines used in outpatient care through voluntary private health insurance plans; and Germany and the United Kingdom (England), where every marketed drug is funded unless explicitly excluded from coverage (Box 4 for more details).

Box 4. Four countries do not establish positive lists for drugs at the central level

In Canada, medicines used in hospitals are funded through hospital payments and each hospital defines its own formulary (i.e. positive list). Medicines used in outpatient care are not covered under the Canadian Health Act (universal coverage system). Two-third of Canada's residents get pharmaceutical coverage from supplementary private health insurance, voluntary in all provinces and territories except Québec, and the remaining third get coverage from public plans developed by federal, provincial or territorial governments (mainly for seniors, beneficiaries of social benefits or patients with costly conditions). Public plans develop their own formularies, while private drug plans use positive lists, negative lists, or provide coverage for all drugs approved for marketing in the country. In Québec, a positive list defines medicines covered by public plans, and private plans must cover at least those in this list.

In the United States, residents are covered through private plans or through public plans (Medicare, States' Medicaid or the Veteran Health Administration). Every individual insurer draws its own formulary (positive lists). Insurers operating Medicare part D face some constraints as they are required to cover all existing drugs in some therapeutic classes, (Franck, 2012) but other insurers have been generally free to determine the range of pharmaceuticals covered until 2014. The ACA now requires some private plans to cover "essential health benefits" (see Box 3 for more details).

In Germany, the law excludes three categories of drugs from reimbursement: pharmaceuticals used in adults for the treatment of minor ailments (e.g. drugs used in the treatment of cold and flu syndrome, including cold medications, cough suppressants and expectorants, and pain killers; mouth and throat medications other than antifungal; laxatives; and drugs for motion sickness); over-the-counter drugs unless they are prescribed to children up to 12 years (up to 18 years in certain cases) or they are used in standard treatment of serious diseases according to guidelines established by the Federal Joint Committee; and pharmaceuticals whose main indication aims to improve the of quality of life, particularly treatments of the erectile dysfunction, smoking cessation treatments, slimming drugs, appetite suppressants, anti-obesity drugs, and capillary treatments. The law states that the Minister of Health, in accordance with the Ministry of Economy and Labour and with Parliamentary approval, may further exclude from reimbursement medications pertaining to one of the following categories: pharmaceuticals mainly used in the treatment of minor health disorders and so-called "non-economic pharmaceuticals", defined as pharmaceuticals which contain unnecessary active ingredients, pharmaceuticals whose therapeutic benefit is not proven. This last category corresponds to a list of products, referred to in Germany as the "negative list" (Paris and Docteur, 2007).

In the United Kingdom (England), every product marketed is covered by default but two "negative lists" introduce some restrictions: Schedule 1 lists the drugs, medicines and other substances which cannot be prescribed within the National Health Service (NHS) and Schedule 2 lists those products which can only be prescribed in certain circumstances. In addition, local NHS organisations (Clinical Commission Groups from 2014) develop local "prescribing lists", which aim to ensure clinically appropriate and cost-effective prescribing. Formulary choices, however, are not binding upon prescribers. Hospitals also draw their own formularies.

2.5. Implicit and explicit definitions of benefits covered have both advantages and drawbacks

18. In principle, an *implicit definition* gives more choice to health care providers and patients, and it does not impose any "regulatory" delay in the adoption of new technologies. In practice, however, there is no implicit system without any form of "priority setting" or, in other terms, "rationing". Wherever a budget constraint exists, rationing has to take place at different levels and under different forms: health care denial, waiting times, etc. (Klein, 2012).

19. An implicit boundary of health care coverage leads to priority setting at the local level in countries with decentralised health systems, possibly leading to regional variations in health care coverage. Some mechanisms exist to minimise within-country variations. In Denmark, for instance, patients are allowed to seek treatment anywhere in the country and the home region is required to cover expenses if it declines to provide a service provided by another. In Finland, complaint mechanisms are set up and patients can appeal to an administrative court if they feel that they have not received necessary care. In England, the National Institute for Clinical Excellence and Public Health (NICE) was created in response to unequal access to expensive treatments due to decisions made by local providers facing budget constraints. It aims to provide guidance to all NHS commissioners, providers and patients about cost-effective treatments.

20. An *explicit definition* of the benefit package, by contrast, implies "listing decisions", that may allow a better allocation of resources towards more effective or more cost-effective health care interventions if the decision-making process for medical technologies is well designed. Listing decisions, however, can take time and delay the adoption of a useful technology. To mitigate this effect, some countries have implemented processes to provide access to very innovative or promising technologies, especially when they are used in the treatment of severe and/or life-threatening disease with no therapeutic effect. In France for instance, medicines fulfilling these criteria can be financed prior to marketing authorisation, through the Temporary Authorisation for Use (ATU) scheme. This funding can be extended until the coverage decision is made.

3. Assessment/appraisal and decision-making processes are generally inclusive and transparent

21. All OECD countries have determined a process to make coverage decisions, which is used on an occasional basis in countries where the range of benefits is defined implicitly and more systematically where the benefit package is defined explicitly by positive lists. To some extent, differences in health systems characteristics shape the institutions in charge of assessment and decision-making. Most often, however, countries have a two-step process involving institutions operating at the central level (section 3.1). Bodies in charge of assessment often involve a wide range of stakeholders (section 3.2), while decision-making bodies tend to be less inclusive and the minister responsible for health most often has the last word in coverage decisions (section 3.3). Good institutional arrangements promote transparency and integrity and manage conflicts of interests during assessment and decision-making processes (section 3.4).

3.1. Most countries have a two-step centralised process to make coverage decisions on new technologies

22. The decision-making process of including new technologies in the range of benefits covered consists in theory of two separate steps, but *in practice* it involves three steps. The Belgian Health Care

Knowledge Center, KCE, (2014) describes this process in greater detail in a study on coverage of pharmaceuticals:

- The assessment phase aims at quantifying the clinical, pharmacotherapeutic and pharmacoeconomic outcomes of the new technology as compared with its alternative(s). It is purely descriptive.
- The appraisal phase seeks to evaluate the societal value of the new technology by weighing all relevant decision criteria, including the assessment criteria and other societal considerations, where relevant.
- The decision-making, which is often based on the outcome of the appraisal.

23. These three phases, however, are not always identified as separate steps in the process. Most countries have a two-step process, in which a first body assesses/appraises the new technology and issues recommendations and a second body is responsible for the coverage decision (Le Polain et al., 2010). A few countries entrust a single entity to perform assessment, appraisal and decision-making (e.g. NICE in England and Wales, the Pharmaceutical Pricing Board in Finland, and the Dental and Pharmaceutical Board in Sweden).

24. About two-third of OECD countries have a fully centralised process because the range of benefit covered is defined –implicitly or explicitly- at the central level (see Table 2). In countries with decentralised health systems, assessment and decision-making occur at different levels, depending on the way responsibilities are shared between levels of governments:

- Assessment and decision-making take place at the federal level where benefits are covered by a federal/national scheme (e.g. medicines used in the community or in private hospitals in Australia) or where positive lists are defined at the central level (e.g. medicines in Switzerland and Sweden, all technologies in Spain).
- Assessment can be performed at the central level, via a collaborative platform, but then, sublevels of governments make coverage decisions for their own jurisdiction (e.g. coverage of medicines covered by provinces and territories (P/T) public plans in Canada).
- Assessment (when performed) and decision-making are left at the discretion of sub-levels of governments when they are responsible for funding and providing services for the population (e.g. hospital services in Australia, devices and procedures in Norway, all medical technologies but medicines in Finland).

Centralised assessment/appraisal and decision making							
Systematic							
Australia (medicines, MD and procedures covered by Medicare)							
Belgium (all technologies)							
Chile (all technologies for GES)							
Czech Republic (medicines)							
Denmark (medicines)							
Finland (medicines used in outpatient care)							
France (all technologies)							
Greece (all technologies)							
Hungary (all technologies)							
Iceland (medicines)							
Israel (all technologies)							
Japan (all technologies)							
Korea (all technologies)							
Luxembourg (all technologies)							
The Netherlands (all technologies)							
Norway (medicines used in inpatient and outpatient care)							
Poland (all technologies)							
Portugal (medicines)							
Slovenia (all technologies)							
Slovak Republic (medicines and devices)							
Spain (all technologies),							
Sweden (medicines)							
Switzerland (medicines)							
Turkey (all technologies)							
Occasional							
Switzerland (procedures)							
United Kingdom- England (all technologies)							
Centralised assessment and decentralised decision-making							
Canada (medicines covered by public plans)							
Assessment and decision-making at decentralised level							
Finland (procedures, medical devices)							
Norway (procedures, medical devices)							
Decision at decentralised level, without systematic assessment							
Australia (hospital services,)							
Canada (hospital services, medical devices)							
No assessment and no decision-making							
Iceland (procedures, medical devices)							
Portugal (procedures, medical devices)							
Slovenia (medical devices)							

Table 2. Characteristics of the assessment/ appraisal and decision-making process in OECD countries

Source: 2014 OECD Health Benefit Basket Questionnaire

3.2. Bodies in charge of assessment/appraisal of new technologies often involve a wide range of stakeholders, along with scientific experts

25. The assessment phase primarily relies on expertise. Bodies in charge of assessment often include scientific experts (see Figure 1), but the technical and scientific part of the assessment can also be executed by commissioned experts or technical services of HTA agencies. Institutions responsible for assessment sometimes go beyond this technical assessment and are expected to exert judgements, taking into account a

number of pre-defined criteria which are not only technical and scientific but also others, such as societal values (more details in section 4). Hence, these institutions also include a range of stakeholders to reflect different perspectives during assessment and appraisal process (see Figure 1).

26. The scope of stakeholders involved in assessment/appraisal bodies varies across countries, and sometimes across technologies. In a few cases, assessment/appraisal bodies only include scientific experts (Figure 1). In Japan and Spain, for example, recommendations for coverage are actually issued by an "appraisal body" which includes a wider range of scientific experts. In another set of countries, assessment bodies only include representatives of the government and/or public payers (e.g. Greece for medical devices and Slovenia and Turkey for devices and procedures). Many assessment/appraisal bodies include health care professionals' representatives in addition to experts and public payers or government.

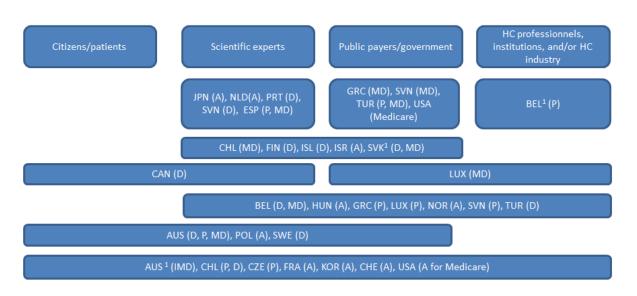


Figure 1. Composition of bodies in charge of assessment/appraisal in OECD countries

Notes: A = all technologies; P = procedures; D = pharmaceuticals; MD = medical devices, IMD = Implantable medical devices; 1. Includes PHI, NLD: Other representatives are also represented in assessment/appraisal bodies.

Source: 2014 OECD Health Benefit Basket Questionnaire

27. The private sector is rarely represented in assessment bodies. The health care industry is sometimes represented, e.g. in Belgium for pharmaceuticals and devices and in Greece for procedures. Representative of private health insurers are members of assessment bodies in Belgium (for procedures) and in the Slovak Republic (for pharmaceuticals and medical devices). Some countries also involve the public and patients in making assessment decisions (see section 4.4 for further details).

28. Institutional arrangements set up for assessment of different medical technologies vary across countries (see the list of institutions involved in each country in Annex Table A.1). While eight countries (e.g. Chile, Hungary, Israel, Korea, the Netherlands, Poland, Spain and the United Kingdom (England)) assign one institution to carry out the assessment of all new medical technologies, fifteen countries have a separate assessment body by type of medical technologies. For example, France has three different commissions for medicines, medical devices and procedures separately though all of them are part of the National HTA agency (HAS). A similar structure with three different assessment bodies is also found in

Greece. In a few countries, one body is in charge of assessment of pharmaceuticals, while other technologies are assessed at local level (e.g. Finland) or not systematically assessed (e.g. Denmark). While technology-specific assessment bodies allow a higher degree of specialisation from their members, having a single body has the advantage of exerting and accumulating expertise, adopting similar criteria for all technologies and clarifying opportunity costs of adopting one technology over another.

3.3 The minister responsible for health usually has the last word in coverage decisions

29. As opposed to the diversity of stakeholders involved in the assessment/appraisal phase, coverage decisions of medical technologies are most often made by an institution operating at the central level. This is the case in 13 countries for all types of technologies. In most of these countries, the Ministry in charge of health (MoH) is responsible (e.g. Belgium, Korea) (see Figure 2 and Annex Table A.1 for details).

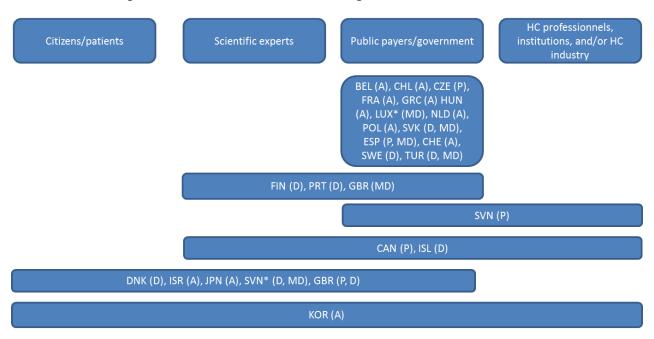


Figure 2. Stakeholders involved in coverage decisions in OECD countries

Source: Notes: All = all technologies; P = procedures; D = pharmaceuticals; MD = medical devices; 1. Includes PHI; * the insured are represented through employees' representations. Source: 2014 OECD Health Benefit Basket Questionnaire

30. In countries with social/mandatory health insurance, payers sometimes have the full responsibility for coverage decisions for some types of technologies (e.g. for medical devices in Czech Republic, for both medical devices and pharmaceuticals in Slovenia, and for pharmaceuticals in Luxembourg), but this is rare. Frequently, the Ministry in charge of health makes decision although health insurers may be responsible to comply with budget constraints.

31. In countries with multiple insurers, however, the MoH generally shares its responsibilities with health insurers (e.g. Chile, Greece) or with other stakeholders. For instance, the Dutch Parliament may be consulted in some cases and Israel also involves the Ministry of Finance and the Health Council (an advisory committee) in decision-making.

32. Residence-based, decentralised health systems make at least some coverage decisions at the sublevels of governments. For example, in Norway, coverage decisions concerning procedures and medical devices and medicines used in an inpatient setting are made at the regional/hospital level, while coverage decisions pertaining to drugs listed for general reimbursement involve the Medicines Agency (NoMA), the Ministry of Health and the Parliament.

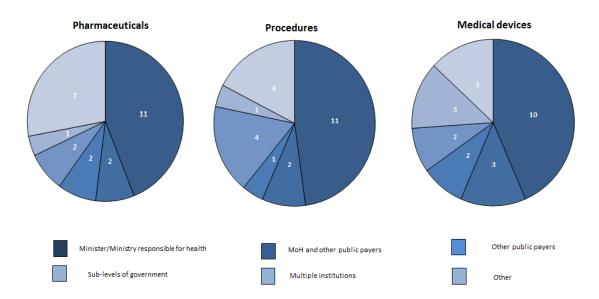


Figure 3. Bodies responsible for coverage decisions in OECD countries (N=27)

33. The strong involvement of the Ministry in charge of health in decision-making provides some legitimacy to the process (Figure 3). It is also consistent with the fact that in many countries, this Ministry is also involved in the process of budgeting for health. Although there is generally no formal link between budgetary decisions and decisions pertaining to the range of benefits covered, having all responsibilities in the same hands encourage consistency. In most countries, however, coverage decisions are made one after another to ensure timely access to new technologies, which does not allow a comprehensive review of overall budget impact of all new technologies covered. An important issue in this respect is whether decision making should be only specific to the technology in question, or whether it should in some way, take a broader outlook. In Israel, the "health basket committee" makes recommendations for coverage once a year with an overall budget expected to cover all new technologies included in the positive list. This strategy has a large inconvenient of possibly delaying the adoption of useful technologies, but has the merits to clarify opportunity costs of new technologies.

3.4. Good institutional arrangements promote transparency, integrity and manage conflicts of interests

34. A decision-making process that is inclusive aligns incentives and expectations of different actors effectively and builds upon reliable information. "This facilitates an engagement process that achieves credible commitments and is conducive to citizens' trust in institutions and co-operation for implementation (OECD, 2015d)".

35. In countries with best practices, such as Australia, France or Japan, criteria for assessment and appraisal are publicly available, as well as results and recommendations, so that stakeholders involved directly in making assessment and appraisal decisions and other interested parties are informed of the process, information needs and criteria for making decisions. Specifically, a transparent process implies:

Note: number in the pie chart refers to the number of countries in the specific category. Source: 2014 OECD HBB Questionnaire

- The publication of information on the process, and criteria for making decisions, including HTA guidelines laying out data requirements and assessment criteria. Many countries have developed HTA guidelines, more often for pharmaceuticals than for other types of technologies, and they are usually made publicly available. These guidelines lay out data requirements and also the specific decision-making criteria against which information will be assessed.
- The publication of information on the results of the assessment and the rationale for coverage decisions. The publication of information on the rationale behind assessment and coverage decisions is important as it enables a wide range of stakeholders to take ownership of the process and decisions, anticipate decisions for emerging medical technologies, and possibly contest decisions made. This can take several forms, such as detailed records of meetings, summary of meetings, and assessment reports. About half of OECD countries publish information on assessment and recommendations for coverage for all or some technologies, as shown in Table 3 and transparency is assured consistently in Belgium, Japan, Norway and the United States (Medicare) by different forms of information. In countries such as the Czech Republic, Denmark (for pharmaceuticals), France, and Sweden, such information is published on a dedicated website and easily accessible.

Table 3.	Public availability of minutes of the meetings, assessment reports and rationale for coverage
	decisions

	Minutes of meetings	Assessment reports	Recommendations for coverage	Rationale for coverage decisions
Yes	AUS (P, D), BEL, CHL, CZE (P), FRA, GRC (P, D), ISR, JPN (P), NOR, POL, SVK (D, MD), SVN, ESP (P, MD), GBR (P, MD), USA	(D), GRC (P, D), JPN (P, D), NLD, NOR, POL, PRT (D), SVK (D, MD), ESP (P,	AUS (P, D), BEL, CAN (D), CHL, CZE (P), FRA, GRC (P, D), HUN, ISL (D), ISR, JPN, KOR, NLD, NOR, POL, SVK (D, MD), SVN, ESP (P, MD), GBR (P), USA	AUS (D), BEL, CHE (D), CZE (D), DNK, FIN (D), FRA, ISR, JPN, NOR, SVN, SWE (D), GBR, USA
No	AUS (MD)*, CAN (P, D), HUN, ISL (D), JPN (P, MD), KOR, LUX (P, MD), NLD, CHE, TUR,	CZE (P), HUN, ISL (D), ISR, JPN (MD),	AUS (MD), CAN (P), LUX (P, MD), CHE, TUR	CAN, CHE (MD, P), CHL, ISL (D), KOR, POL, TUR
Not applicable	-	-	-	AUS (P, MD), LUX, NLD, PRT

Source: Note: P = procedures, D = drugs, MD = medical devices. AUS: Except for MD considered by Medical Services Advisory Committee (MSAC); CHE: Assessments will gradually begin to be published from 2016; USA: Medicare only. Source: 2014 OECD Health Benefit Basket Questionnaire

36. Maintaining the independence of bodies in charge of assessment and appraisal is challenging but may be facilitated by public funding and the management of conflicts of interests. Many countries fund these bodies through public sources though in some cases they are complemented by users' fees (to be paid by applicants, most often health care industries). For instance, in Canada (for pharmaceuticals), Greece (for procedures) and Hungary, assessment bodies are funded by governments and industry (through user fees for applications), while in Australia (for medical devices), Greece and the Slovak Republic (both for pharmaceuticals and medical devices), they are funded solely by industry fees. Also, in most countries, members of assessment bodies are required to declare potential conflicts of interests (Figure 4). Such declaration, however, is not required for members of assessment bodies in a small number of countries (e.g. Czech Republic, Ireland, Luxembourg and Turkey). Where coverage decisions are not directly made by the Minister in charge of health, countries also try to manage potential conflicts of interest.

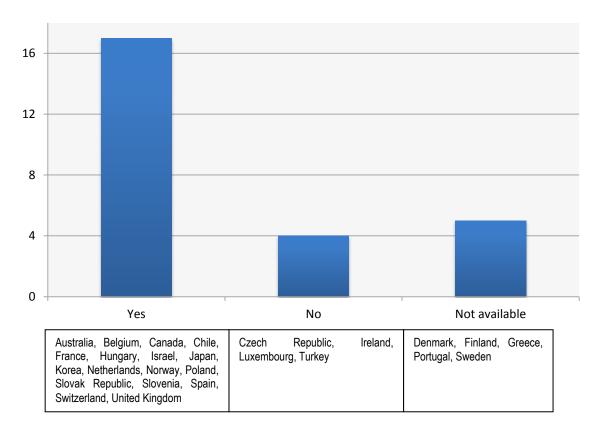


Figure 4. Declaration of conflict of interest in bodies responsible for assessment/appraisal (N=26)

Source: Note: This table only includes only one response per country. When the situation differs across technology-specific assessment bodies, the country has been considered to manage conflicts of interests; declaration of interests is required in at least one of these bodies. Source: 2014 OECD Health Benefit Basket Questionnaire

4. The process for inclusion of a new technology relies on a well-defined set of criteria combining results of health technology assessment with value-based judgements

37. In countries which set a boundary of health coverage based on negative and/or positive lists, new medical technologies are assessed and coverage decisions are made, most often based on a well-defined set of criteria, which can, however, vary across technologies and across jurisdictions. Although criteria for decision-making are not explicitly defined in some cases (e.g. in Slovenia and Japan for new medical procedures and Luxembourg for new medical procedures and devices), criteria generally include results from health technology assessment (HTA) examining clinical and economic evaluation of new technologies (section 4.1). However, HTA raises a number of challenges (section 4.2) and OECD countries consider other criteria, along with HTA results to make decisions (section 4.3). In order to adequately consider all criteria, OECD countries might require innovative approaches (section 4.4) and need to involve a wide range of stakeholders including public and patients during the decision-making process.

4.1. Evidence on comparative effectiveness and economic evaluation are often required, especially for medicines

38. An increasing number of countries use HTA to provide scientific and technical evidence related to new medical technologies during assessment and decision-making processes. However, its use and systematic application varies across countries and technologies. While 19 OECD countries reported a systematic use of HTA in order to decide whether a *new medicine* should be covered, only 9 OECD countries did so for decisions pertaining to new *medical procedures*, and 8 for new *medical devices* (Table 4). Only 10 countries use HTA to inform coverage for *all* technologies, either systematically (e.g. Chile, France, Israel, Korea, Poland) or only in some circumstances (e.g. Austria, Denmark, Mexico, Spain, United Kingdom). Contrary to a general trend, a minority of countries (e.g. the Czech Republic and the United States) never or rarely use HTA as a formal part of coverage decision-making.

Table 4.	Number of countries using HTA systematically or occasionally to make coverage decisions or to set
	reimbursement level or price

Types of technologies	Use of HTA to make coverage decisions	Countries					
	Systematically	Australia, Belgium, Canada, Chile ¹ , Finland, France, Hungary, Ireland, Israel, Italy, Korea, Luxembourg, Netherlands, New Zealand, Norway, Poland, Slovenia, Sweden, Switzerland					
Pharmaceuticals	In some circumstances	Austria, Denmark, Mexico, Portugal, Spain, United Kingdom					
	To determine reimbursement level or price	France, Hungary, Ireland, Japan, New Zealand, Norway, Poland, Sweden, Hungary					
	Systematically	Australia, Chile ¹ , France, Hungary, Israel, Korea, Netherlands, Poland, Slovenia					
Procedures	In some circumstances	Australia, Austria, Belgium, Canada, Denmark, Finland, Ireland, Italy, Luxembourg, Mexico, New Zealand, Norway, Spain, Sweden, Switzerland, United Kingdom					
	To determine reimbursement level or price	Israel, Japan, United States					
	Systematically	Australia, Chile ¹ , Belgium, France, Hungary, Israel, Korea, Poland					
Devices	In some circumstances	Canada, Estonia, Ireland, Norway, Sweden, Austria, Denmark, Finland, Italy, Luxembourg, Mexico, Netherlands, New Zealand, Spain, Switzerland, United Kingdom					
	To determine reimbursement level or price	France, Israel, Japan					

Notes: 1. Only for products and services to be included in GES (explicit guarantees expected to be covered by all plans)

Source: 2014 OECD Health Benefit Basket Questionnaire and OECD Health Systems characteristics survey, 2012

39. HTA is usually undertaken based on developed guidelines. Some countries including Chile, Hungary, Korea, Luxembourg, Poland and the United Kingdom have developed general guidelines to be used for all types of medical technologies but countries have generally developed specific guidelines for each type of technologies, notably pharmaceuticals.

40. In order to inform coverage decisions, all OECD countries using HTA assess the **clinical value** of new technologies. The evaluation of clinical value often includes an assessment of the comparative effectiveness of the new technology, relative to the standard of care. "Non-inferiority" is often a prerequisite to consider coverage. For example, in the Netherlands, a new medicine must be as effective, or more effective, as the standard treatment for a certain illness, and in Australia, "the extent to which a proposed treatment represents a clinically meaningful advance in therapy" is one of the criteria considered. Nonetheless, new technologies with no demonstrated added clinical value over standard care are often granted coverage in many health systems.

41. The methodology used to assess clinical aspects is similar across countries but the outcomes might differ. While many countries refer to gains in quality-adjusted life years (QALYs) when defining "clinical benefit", others only use rating⁴ (e.g. in France for drugs and medical devices, in Germany for drugs). In addition, HTA agencies may have different requirements in terms of evidence levels accepted, outcome measurements such as mortality, morbidity, longevity and quality of life, or choice of a comparator to assess comparative effectiveness. As a result, HTA agencies sometimes reach different conclusions about the clinical benefits of the same technology. For example, a treatment for multiple sclerosis assessed in several countries was found to have "no added value" over comparators in Sweden and minor clinical benefits in other countries (Paris and Belloni, 2013).

42. **Economic evaluation** plays an increasingly important role in a number of countries as part of HTA. Economic evaluation allows decision-makers to consider the relative and potentially the absolute value of alternative uses of available resources. Economic evaluation includes a wide range of different perspectives and methods, which are designed to compare two or more alternatives in terms of costs and outcomes (See box 5). Twenty-seven OECD countries reported performing economic evaluation when assessing health technologies, particularly for pharmaceuticals (See Table 5). Most HTA agencies accept or require cost-effectiveness and/or cost-utility analyses, and prefer cost-minimisation analysis when the new technology is no more effective than existing ones.

Box 5. Economic evaluation: methods and choice of comparators

Economic evaluation encompasses a range of widely accepted analytical methods, which mainly differ by the way outcomes are considered. Cost-consequence analysis (CCA) only looks at incremental costs of a new technology without consideration of outcomes. Cost-minimization analysis (CMA) is usually used to compare two technologies with similar outcomes. Cost-effectiveness analysis (CEA) compares costs and outcomes where outcomes are measured by a natural uni-dimensional index of outcome (e.g. a life year, or the occurrence of myocardial infarction). Cost-utility analysis (CUA) also compares costs and outcomes are measured in QALYs, which combines survival and utility of different health states. Cost-benefit analysis (CBA), finally, compares costs and benefits of two alternatives where outcomes are given a monetary value (Drummond et al., 2005). Cost-utility or cost-benefit analysis presents the advantage to be comparable across technologies and therapeutic areas.

The **choice of comparators** is different across countries. Some countries such as Australia (for pharmaceuticals, procedures and in vitro diagnostic medical device) and Finland, compare the new technology with the technologies which are most likely to be replaced, while others such as Belgium, Canada (for pharmaceuticals), the Czech Republic, Hungary, Israel, the Netherlands, Norway, Poland, the Slovak Republic (for pharmaceuticals and medical devices), as well as Spain and the United Kingdom compare the new technology with the technologies which are considered routine treatment. In Portugal, the comparator should be the most common treatment used, if not the most efficient, and in Chile, all existing alternative treatments need to be included in the assessment. In Korea, comparative analysis is done against a routine treatment and a treatment alternative with the highest market share.

⁴ For instance, France uses a 5-level scale to rate the added-value of a new medicines by comparison to existing comparators (from "no added value" to "major therapeutic advance"). Germany uses a 6-level scale including "No evidence of additional benefit" and "Less benefit than comparator".

Several countries including Israel, the Netherlands, Poland, Portugal, Sweden (for pharmaceuticals) and the United Kingdom also compare with the most cost-effective alternatives. In Sweden, for example, the costs and health effects of using the drug in question should be compared with the most appropriate alternative treatment (e.g. the most used) and this could be a drug treatment, another treatment or no treatment at all (TLV, 2013).

43. OECD countries adopt different perspectives for economic evaluation (Table 5). The perspective adopted for economic assessment (public payer, health system or societal) determines the types of costs (and savings) taken into account in analyses.

- The *public payer perspective* is adopted by more than half of OECD countries and generally takes into account direct medical costs (the cost of the product itself and associated medical acts, including costs of adverse effects) and potential savings for public payers. In some cases, countries adopting this perspective allow for further considerations of other types of costs. In the United Kingdom (England and Wales), for instance, in situations where costs outside this perspective are considered to be 'significant', they should also be presented alongside the Reference Case analysis (Paris and Belloni, 2013). In Belgium, indirect costs are also included in the assessment of pharmaceuticals, whereas the Canadian Drug Expert Committee (CDEC) generally considers direct medical costs but includes the indirect medical costs for some specific drugs.
- The *health system perspective* is less often used (by 12 OECD countries); it generally takes into account direct medical costs and savings for all payers including patients and private insurers, where relevant. In Poland, for instance, medical costs for public insurers and patients are included in the economic evaluation.
- The *societal perspective* is also common and accepted by 13 OECD countries. It considers a wide range of costs and benefits beyond the health systems: direct medical costs, indirect medical costs, direct non-medical costs, indirect non-medical costs and savings such as productivity gains. The Netherlands, for example, lays out specific data requirements for direct and indirect costs within and outside the health care system. In Norway, economic evaluations consider indirect medical costs (medical costs not related to the disease treated by the technology), direct non-medical cost (e.g. transports, time for patients) and indirect non-medical costs (e.g. loss/gains in labour productivity and sickness leave).

44. OECD countries most often indicate a *preferred* perspective, but allow applicants to present additional information based on other perspectives. Additional data such as direct non-medical costs and indirect costs are usually used as supplementary information when making coverage decisions and are sometimes required in addition for certain cases.

	Perspect	ive accepted f	or economic ev	valuation	
	Economic evaluation	Public payer perspective	Health system perspective	Societal perspective	Affordability or budget impact
Australia	•	•	•	•	•
Austria*	•	•	•	0	Not available
Belgium	•	•	0	•	•
Canada			0	0	•
Chile	•	•	0	•	•
Czech Republic			0	0	•
Denmark	0	0	•	0	0
Estonia*		Not available	Not available	Not available	Not available
Finland	•	0	0	•	•
France		•	•	0	0
Germany*	Not available	Not available	Not available	Not available	Not available
Greece*		0	0	0	•
Hungary	•	•	0	0	•
Iceland	Not available	Not available	Not available	Not available	Not available
Ireland*	•	•	•	•	•
Israel			0	0	
Italy*	•	•	•	•	•
Japan	0	Not available	Not available	Not available	0
Korea	•	•	0	•	•
Luxembourg	Not available	Not available	Not available	Not available	Not available
Mexico*	•	0	•	0	•
Netherlands		0	0		0
New Zealand*	•	0	•	0	•
Norway			0	•	•
Poland	•	•	•	0	0
Portugal		•	•	0	•
Slovak Republic	•	•	0	0	0
Slovenia		•	0	0	
Spain	•	•	•	•	•
Sweden	0	0	0		0
Switzerland	•	0	•	•	0
Turkey		0	0	0	0
UK	•	0	0	•	0

Table 5. Inclusion of economic evaluation in health technology assessment and the perspectives adopted for economic evaluation

Note: ●=yes ○=no. Source: 2014 OECD Health Benefit Basket Questionnaire and *2012 OCED Health System Characteristics Survey.

45. In a majority of OECD countries, economic evaluation includes affordability or *budget impact analysis* (*BIA*) (Table 5). Although different specifications may be used, BIA generally refers to an analysis of the financial impact of funding a new medical technology for a finite period. The time horizon for BIA is usually short and BIA reports the costs for each year in which they occur. Some assessment

bodies have produced guidelines for BIA: the Institute for Quality and Efficiency in Health Care in Germany (IQWiG, 2009), the Health Information and Quality Authority for Ireland (HIQA, 2010), the Agency for Health Technology Assessment (AOTM) in Poland (AOTM, 2009), the Pharmaceutical Benefits Advisory Committee (PBS) for Australia (PBS, 2015), and the Patented Medicine Prices Review Board (PMPRB) in Canada (PMPRB, 2007).

46. Until recently, the role played by budget impact in the decision to fund (or not) a technology has not been clear and in many countries high budget impact has not been likely to justify a negative decision if a drug was considered to be eligible for coverage according to other criteria (Paris and Belloni, 2013). In two countries, a high budget impact changes the level of decision-making. In Norway, the Parliament makes the reimbursement decision if the budget impact of outpatient medicines is expected to exceed NOK 25 million in the 5th year after marketing. Similarly, in Australia for medicines, the Minister of Health must refer to the Cabinet if the annual net cost of listing a new medicine is more than AUD 20 million in any of the four years of the forward estimates. In some countries (e.g. France and the Netherlands), the expected budget impact determines whether a medicine will be subject to economic evaluation to inform decision-making. Below a certain threshold, economic evaluation is not required.

47. Current trends in pharmaceutical spending might force countries to clarify the role of budget impact analysis in their decision-making process. In the case of hepatitis C treatments, where the new medicines were considered to be cost-effective for sub-groups of patients, many countries decided to restrict access for the most severely affected patients because they could not afford to treat all patients. In several countries, the argument of "affordability" was officially used for the first time to restrict access to an effective treatment.

4.2 HTA faces a number of challenges

48. Although economic evaluation is now part of the decision-making process in many countries, it raises a number of questions and challenges. Questions related to the theoretical foundations and the appropriateness of methods currently used, generate ongoing debates (see Box 6). Beside these theoretical and methodological issues, other challenges affect current practices of HTA: they pertain to the availability of evidence at the time of assessment; the difficulty to set an incremental cost-effectiveness ratio (ICER) threshold beyond which new technologies will not be considered to be cost-effective; and the costs and benefits of the HTA process itself. The rest of the section describes the first two challenges which lead to discussions in section 4.3 on the importance of considering other criteria for coverage decisions along with HTA results. The latter two challenges will be addressed in section 7, together with the approaches taken across countries at least partly to overcome them as they refer to reconsideration of the role and focus of HTA.

Box 6. Cost-utility analysis: ongoing research and debates

A number of different analysis approaches have been used in economic evaluation and cost-utility analysis has increasingly been adopted. The primary outcome of a cost–utility analysis is the incremental cost per QALY gained, most often referred to as the "incremental cost-effectiveness ratio (ICER)". It is calculated as the difference in the expected costs of two interventions, divided by the difference in the expected QALYs produced by these interventions. The ability of the QALY to combine duration and quality of life and its ease of use explain its success.

But the worldwide adoption has also generated ongoing research and debates in relation to this analytical approach. For example, there are discussions around the measure of outcomes itself "the QALY". First, an implicit assumption that underlies this approach is that all QALYs are of equal social value, as summarised in the formula "a QALY is a QALY". In practice, this means that a QALY gained has the same value, whatever the condition treated or the personal characteristics of the population treated, including age, sex, severity of disease, level of deprivation, social role of individuals, and other individual characteristics (Whitehead and Ali, 2010). For instance, a QALY gained for an 8-year child has the same value as a QALY gained for an 88-year old patient. Utility weights were

developed and attributed to different health states and used to adjust years of life gained by their "utility" (or quality of life), but they also raise a number of technical and ethical issues. Studies have shown that these utilities were not transferable from one context to another. Finally, the use of QALYs for making coverage decisions, can be problematic because the total amount of QALYs gained may increase faster for a benign condition that affects many people than for a serious condition but with reduced incidence. In Oregon, this approach led to the prioritisation of the prevention of caries over appendectomy in the first version of the list of the benefits covered (Fleurbaey et al., 2012).

49. At the time of assessment of new technologies, **the evidence available is often limited**, and typically scarcer for procedures which are not subject to "marketing authorisation", than for medicines. Noting this challenge, countries often adapt data requirements to data availability. In Australia, for example, there are no minimum evidence requirements for assessing any medical technologies, and each body expects the best available evidence, published or unpublished, to be presented that can be used to compare the proposed intervention with its main comparator. For example, although the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) for medical procedures and in vitro diagnostic medical device have a strong preference for clinical and economic evaluations that are based on randomised trials that directly compare the proposed intervention with the main comparator (direct randomised trials or head-to-head trials), the committees also recognise that such trials are not always available. Similarly in other countries including Hungary, the Netherlands, Norway, Switzerland, and the United Kingdom; although randomised control trials are preferred, the best available evidence is used for the technology assessment where ideal data are not available.

50. **Countries have been reluctant to define and publish an Incremental Cost-effectiveness ratio** (**ICER**) **threshold**, partly because of the difficulties in setting up such a benchmark (Cleemput et al., 2008). Some analysts argue that defining and publishing ICER thresholds may incentivise manufactures to set prices close to the threshold, also referred to as "strategic pricing". Since the ICER threshold often is associated with the willingness to pay for health gains, analysts have tried to define the ICER threshold more clearly. As a result, the World Health Organization has suggested that health interventions with an ICER less than equal to GDP/capita could be considered very cost-effective, while interventions with an ICER between 1 and 3 times GDP/capita would be considered cost-effective, and other interventions would not be cost-effective (Bertram, 2015). Other economists advocate for a threshold set by reference to the cost-effectiveness of interventions currently used in health care (Claxton et al., 2015).

51. At the time of the OECD survey (2014-2015), only five countries including Hungary, Korea, Poland, the Slovak Republic and the United Kingdom, had published an ICER threshold range; 2 to 3 times GDP per capita in Hungary, GDP per capita in Korea (may vary by disease), 3 times GDP per capita in Poland, EUR 18 000 to 26 500 in the Slovak Republic and GBP 20 000 to 30 000 in the United Kingdom. Nonetheless, ICER threshold rarely serves as a cut-off point above which coverage is systematically denied in these countries as other criteria are often given greater weight when making coverage decisions (section 4.3). While the non-publication of an ICER threshold allows more flexibility in the appraisal of a technology and prevents strategic pricing from pharmaceutical companies, having a benchmark to make a diagnosis on the costs-effectiveness of a new technology sounds useful.

4.3. Other criteria are considered for decision-making, along with HTA results

52. In most countries, comparative effectiveness and cost-effectiveness are not the only criteria taken into account to inform coverage decisions. The set of criteria considered along with HTA results is often well defined and publicly available. It varies across countries:

• The burden of disease or public health impact of the disease treated is considered an important criterion in several countries. Chile, for instance, has explicitly used the burden of disease as

criterion for prioritisation for the Plan of Explicit Health Guarantees (GES), a national program mandatory for public and private health insurers that covers the benefits for 80 health conditions.

- The *feasibility of technology implementation in the health system* is explored in some countries. For instance, countries such as Canada, Chile and the Czech Republic assess the resource availability and requirements in the health system for covering medical procedures, and in Norway, potential organisational changes following the implementation of a new technology may be considered.
- The ability to target therapy to those likely to benefit most is sometimes evaluated. In Australia, assessment criteria also include the scope for use of the drug beyond any restriction for subsidy, and the extent to which a restriction can be constructed that satisfactorily distinguishes use that is acceptably cost-effective from use that is not cost-effective.
- Several countries such as Australia, Chile, Israel and the Netherlands consider the cost implications to patients in order to *avoid patients facing catastrophic health expenditures* in the event of disease.
- Some countries refer to *international experiences*. Hungary considers the use of new medical technologies abroad as one of the criteria to inform the process of making coverage decisions in the national context and Korea also refers to coverage in other countries as one of the criteria for making coverage decisions.
- Some countries apply *societal values* as part of criteria for making coverage decisions.
 - For example, several countries including Australia (for pharmaceuticals) and Chile explicitly use the *rule of rescue* for serious diseases for which there is no treatment available.
 - In Sweden, the Dental and Pharmaceutical Benefits Board (TLV) makes decisions using three principles including the *cost-effectiveness principle* which means that the cost of using a medicinal product should be reasonable from a medical, humanitarian and socioeconomic perspective, *the need and solidarity principle*, which means that those with the most pressing medical needs should have more of the health care system's resources than other patient groups, *the human value principle*, meaning that the health care system should respect the equal value of all human life.
 - In Australia, Chile, England and Hungary, *equity* is also considered for coverage decisions for medical technologies. In Australia, sponsors are invited to submit evidence on equity including affordable access and equity assumptions implicit in the economic evaluation. In Chile, twenty-five health conditions that presented greater mortality and prevalence gaps between socioeconomic groups were selected for health care coverage funded collectively, along with seven other conditions associated with gender and sex inequalities. In the United Kingdom (England), NICE must consider the impact of its guidance on health inequalities.
 - Chile uses *social consensus* as one of the criteria for making coverage decisions for GES.

4.4. Adequate consideration for all criteria might require innovative approaches...

53. Making coverage decisions is inevitably difficult due to the many different considerations that come to play and countries have to ensure that multiple criteria are duly considered and weighted against

each other. The use of multiple criteria has fostered the development of new methodologies for assessing new technologies.

54. One way is to use quantitative methods to weigh multiple criteria according to stakeholders' preference. Multi-criteria decision analysis (MCDA) aims to quantify trade-offs between multiple criteria through relative weights, has recently gained attention. It is expected to support decision makers by enabling them to structure complex evidence and exercise judgment, but also allows them to incorporate both objective and subjective considerations in the decision-making process (Singpurwalla, 1999). Several studies have developed frameworks and weighting methodologies to facilitate an integration of MCDA to HTA in practice (see box 7). In a study commissioned by the European Commission on "advanced HTA", Angelis and Kanavos (2015) consider MCDA as an extension of HTA to assess the value of new technologies. Applying their framework and method to a concrete case study (medicines used in the treatment of colorectal cancer), they obtain a ranking of treatment options using the "cost per unit of value" which is very different from NICE ranking using cost/QALY. The authors of this study advocate for the use of MCDA to inform decision-making. Notably, MCDA seems appealing for its ability to make choices more explicit, but to the best of our knowledge, is not yet implemented in practice.

Box 7. Multi-criteria decision analysis: framework and weighting methodologies

A few studies have developed multi-criteria decision analysis (MDCA) framework and methodologies for making assessment and coverage decisions of medical technologies.

A Canadian study proposed a model for integrating MDCA to HTA methods (Goetghebeur et al., 2012). Authors first defined 15 criteria considered for inclusion of a new drug in benefit plans. These criteria were related to disease impact, context of intervention, response outcomes, economics, and quality of evidence. In a second step, a panel of decision makers, specialists, general practitioners, nurses, pharmacists, health economists was asked to assign weights to each criterion. The criteria with the highest weights were assigned to relevance and validity of evidence, improvement of efficacy/effectiveness, improvement of safety, and public health interest. Then, the experts were asked to score the performance of each drug for each of the 15 criteria on a scale from 0 to 3 according to the most up-to-date scientific knowledge. Lastly, each drug was rated and ranked taking into account the weight and score of each criterion.

The Belgian Health Care Knowledge Center (KCE) has also been working to incorporate MCDA as a tool to support health care reimbursement decisions. Based on a previously developed decision framework, KCE conducted a study aiming at measuring the public preference for different reimbursement criteria pooled into three blocks; therapeutic need, societal need and added value of the new intervention relative to the best alternative intervention. A survey composed of nine discrete choice questions was distributed to the general public and decision-makers. Using two different methods (log-likelihood method and the coefficient range), weights were assigned to each criterion. The criteria generating the highest weights among the general public were *disease severity in terms of quality of life under current treatment* and opportunities for improving quality of life through health care interventions. Decision-makers gave more importance to criteria related to *impact on life expectancy* and *prevalence of disease*. Before applying MCDA to HTA and decision-making, further research on how to score diseases and interventions according to each criterion included in the model is needed and is continued in 2015 (Cleemput et al, 2014).

55. Another quantitative approach is adapting ICER thresholds to other measurable criteria. To avoid applying the same ICER threshold to all coverage decisions, countries which have set a defined threshold also give weight to other factors when making coverage decisions for certain technologies. For instance, in the United Kingdom, NICE issued in 2009 a special guidance on end-of-life treatments that include cancer therapies. Under certain criteria, the cost-effectiveness threshold may then be exceeded, suggesting that, for some treatments, greater weight is placed on other factors (patient need, efficacy, ethics and lack of alternative treatments) (Saverno et al., 2012). The Slovak experts in the Categorisation Council/Committee also allow a threshold to be exceeded when the drug in question is used in treatment of rare diseases.

56. In the Netherlands, the National Health Care Institute (*Zorginstituut Nederland*, ZiLN) recently suggested to adapt ICER thresholds to the burden of disease for patients, assessed using "proportional shortfalls" (ZiLN, 2015). This method allows the prioritisation of diseases to be treated according to the number of QALYs *lost* with no treatment (Lindmark et al., 2014). The ZiLN suggests adopting 3 ICER thresholds, increasing with the burden of disease, instead of having a single threshold systematically exceeded in some disease categories. This method is expected to better reflect societal preferences while keeping limits to what is acceptable in terms of cost-effectiveness. It imposes thresholds for future decisions.

4.5. ... and involvement of a wide range of stakeholders including public and patients

57. Another way to weigh multiple criteria against each other is to involve a wide range of stakeholders in the process to adequately represent different perspectives (as seen in sections 3.2, 3.3, and 3.4). Many countries also allow different stakeholders not represented in assessment/appraisal and decisions-making bodies to take part in these processes through specific hearings, public consultations and ad hoc working groups, and provide opportunities to re-evaluate coverage decisions through an appeal mechanism even after decisions are made (Box 8).

Box 8. Stakeholder involvement through specific hearings, public consultations and appeal mechanisms

Several OECD countries allow different stakeholders not represented in assessment/appraisal and decisionsmaking bodies to take part in these processes. In several countries, stakeholders who are not represented in the assessment body can take part in specific hearings and/or public consultations. Even when such hearings and consultations are not part of the formal process, additional stakeholders sometimes have the opportunity to contribute to the assessment decisions process, through ad hoc working groups (e.g. Belgium). A number of OECD countries also allow stakeholders who are not represented in the *decision-making* body to take part in the *decision-making* process. For example, in the United Kingdom, additional experts may be invited to attend and advise the committee responsible for making coverage decisions of different types of medical technologies on a topic- by- topic basis to assist in considering and interpreting the evidence. In Chile for example, a selected stakeholder can take part in making coverage decisions. For instance, the government makes coverage decisions for all types of medical technologies but the National Health Fund is invited to react or comment during the process through specific hearing.

Moreover, many OECD countries have a mechanism of appealing against decisions made to provide opportunities to re-evaluate them if needed. In many countries, such mechanism exists for both assessment results and coverage decisions. For example, in Portugal, a pharmaceutical company whose product is being assessed can appeal against the decision or a specific part of the assessment process. In Israel, an appeal can be made during and after the decision-making process. In some countries, there are multiple channels for making an appeal against coverage decisions. For example, in Denmark, for all types of medical technologies, a complaint can be sent to the Ministry of Health or the decision can also be challenged in court. Similarly, in Canada, individual residents and stakeholder groups may take the province to court to argue that a procedure should be publicly insured.

58. Involving patients, users and the general public in the processes of priority setting will promote the legitimacy, transparency, and accountability, of the process, and is likely to increase trust in the system. It can also give the opportunity to benefit from patient knowledge and experience (van Thiel and Stolk, 2013, Barasa et al., 2015).

59. It can be argued that the general public is indirectly involved through their democratic voting rights because in most OECD countries these criteria for making coverage decisions of new medical technologies are determined by legislation (e.g. the Slovak Republic, Sweden) or by the government (e.g. Hungary) or a combination of both (e.g. Chile for GES plan, Denmark). In several cases, specific assessment and decision-making bodies develop a list of criteria but they complete other criteria defined by law and governments (e.g. Australia for medicines, the Netherlands).

60. Few OECD countries involve patients directly in the process leading to coverage decision of specific technologies. In 7 countries, bodies in charge of assessment or appraisal include representatives of patients, consumers or citizens, who have the same rights as other members and contribute to the decision-making (Table 6). On the other hand, in the Czech Republic and Chile, although patients are consulted during the assessment process, they do not have voting rights for making assessment decisions. In some countries, patient associations are invited to provide their views during assessment and decision-making processes. In Canada, they can provide their input through websites during assessment of pharmaceuticals, and in the United States, public comments are solicited through public consultation for Medicare coverage. In France, users can be invited to express their views through specific hearings and will take part in the assessment process in coming years.

Table 6.	Public involvement in the process of assessment/appraisal of new technologies	
1 4510 01		

	Voting rights / Voice	Consultation		
Patients	Canada (D), Denmark (D), Poland* (A), Sweden (D), Switzerland (A)	N), Chile (P,D), Czech Republic (P)		
Consumers	s Australia (IMD), Korea (A), Switzerland (A)			
Citizens	Australia (P, D, MD), Canada (D)			

Notes: "Voting rights / voice" means that representatives have the same status than other members: voting rights if there is a formal vote, contribution to the debates if the decision is based on consensus. Consultation means that representatives of consumers / citizens / patients are consulted during the assessment process or during the deliberation, but without formal voting rights (by contrast to other members). D= Drugs, P=Procedures, MD=devices, IMD= Implantable Medical Devices, A=All technologies * Ombudsman for patient rights

Source: 2014 OECD Health Benefit Basket Questionnaire

61. However, to ensure patients' effective contribution to dialogue and negotiations, some guidance is needed. England's NICE has developed a program, Public Involvement Programme (PIP), supporting the involvement of patients, carers and the public in NICE's boards and appraisal processes. The PIP provides guidance on patient recruitment process, advice on how to engage in NICE processes and evaluation of involvement opportunities so that patient and carer groups can contribute to technology appraisal effectively.

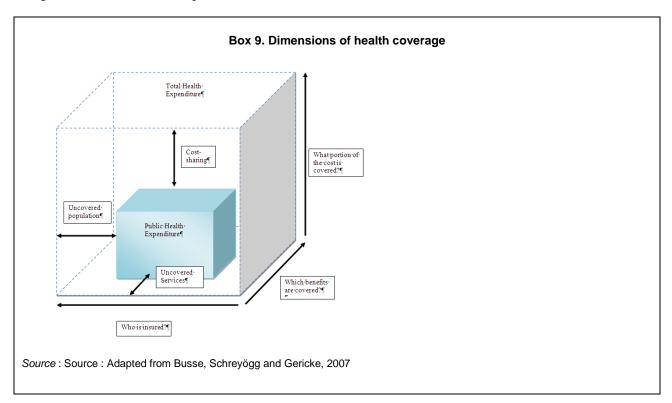
5. Dynamic adjustments of the range of benefits covered are less structured

62. While the process to include new technologies in the range of benefits covered is well-defined, revisions and downward adjustments are not always carefully designed. In the aftermath of the global financial crisis, many OECD countries have adopted cost-containment policies, but they rarely implemented a far-reaching downward adjustment of the range of benefits covered. Instead, they have often increased cost-sharing in order to cope with tighter fiscal situations or introduced restrictions in covered uses (section 5.1).

63. OECD countries sometimes use health technology re-assessment to adjust health care coverage (section 5.2), but this scarcely leads to delisting, even where new evidence does not support continued coverage (section 5.3). In order to promote evidence-based policies in adjusting health care coverage, OECD countries need a formal re-assessment process, transparency about criteria for disinvestment and stakeholders' involvement for making reassessment decisions (section 5.4).

5.1 Far-reaching downward adjustments of the range of benefits covered are uncommon

64. Countries can adjust the range of benefits covered by public funding according to three dimensions: the proportion of cost covered (height), the share of population covered (breadth), and the range of benefits covered (depth) (Busse et al, 2007; Box 9).



65. In the aftermath of the global financial crisis, most often, countries reduced the proportion of cost covered by public funding (*height*) and increased *cost-sharing* (Mladovksy et al 2012; Table 7). For example, France has decreased the reimbursement level of some pharmaceuticals from 35% to 30%, and Denmark increased cost-sharing for fertility drugs. Moreover, Iceland increased cost-sharing twice in 2010 and 2011 for prescription drugs (Vogler, 2011).

66. Frequent implementation of increased cost-sharing across countries can be explained by a combination of factors. It is certainly not desirable to compromise universal health coverage achievements; on the other hand, countries might find it easier to change cost-sharing requirements than a downward adjustment of the range of benefits covered (i.e. disinvestment or delisting).

67. An increase of cost-sharing, however, imposes an additional financial burden to users and thereby might introduce barriers to health care. Increased cost-sharing is known to be effective in reducing inappropriate use of health care services but also reduces the use of necessary and high-value services, especially for the poorest parts of the population (Chaudry et al., 2010; Remler and Greene, 2009). Furthermore, an increase of cost-sharing reduces valuable care such as compliance with drug treatment among the chronically ill.

68. Possible improvements in cost-sharing approaches include:

• Value-based cost-sharing, which modulates cost-sharing in order to assure access to very useful and cost-effective treatments (Frendrick et al., 2001; Thomson et al. 2013). An aspect it is

important to take into account is that people generally overestimate present costs and underestimate future health benefits, and therefore tend to underuse preventive services (Liebman and Zeckhauser, 2008). This suggests that cost-sharing should be minimal for services promoting future health benefits.

• **Maximum reimbursement prices** or "reference pricing" is widely used in the pharmaceutical sector. The maximum reimbursement price is (ideally) set equivalent to the price of the most cost-effective therapeutic treatment option for a given condition which is included in the range of benefits covered. With this policy, patients (and doctors) are still free to select other available treatment options, but patients and/or doctors will be responsible for covering any difference in price between the selected option and the defined maximum reimbursement price. Systematic reviews of this policy showed that maximum reference pricing can induce a switch toward the use of less expensive drugs, mixed evidence of cost shifting to other health care sectors (e.g. hospitals) and no evidence indicating adverse effects on health (e.g. mortality) (Aaserud et al., 2006; Morgan et al., 2009).

69. Adjustment of the *breadth* of coverage concerns changes in population coverage, for example by changing the criteria defining the population groups that are covered. In recent years, some countries restricted *population coverage* for a given technology (Table 7). The Czech Republic and Spain, for example, have reduced public health entitlements for undocumented foreign nationals, except for maternal and acute health services. In Canada, the coverage of eye exams and dental care has been restricted to specific populations and in Switzerland, the coverage of eyeglasses has been limited to partly coverage for children only. Although restricting population coverage often is used following a change in therapeutic value or indication for treatment (e.g. Australia, Belgium, Finland, Japan, Luxembourg, Portugal and Turkey), it may endanger the achievement of universal health coverage, an important achievement in nearly all OECD countries.

70. Adjusting the *depth* of the range of benefits covered is another option available to countries, however delisting a technology from publicly-funded coverage appears to be a policy option rarely used (Table 7). It happens when a technology becomes obsolete, or when it can be justified by unsatisfactory clinical- and/or cost-effectiveness or a price reduction of alternative treatments. For example, over-the-counter (OTC) drugs were delisted in Germany in 2004 (Busse et al, 2014) and in Czech Republic in 2012 (Chytilov'a and Šebesta, 2015). In the Netherlands, the range of benefits covered is reviewed annually, and delisting can occur following this process. The review in 2010 resulted in delisting non-acute care provided outside the European Union, and following the review in 2011, the number of reimbursed primary psychological therapy sessions was reduced from 8 to 5 (Kroneman et al 2015).

	Delisting of benefits (depth)	Changes in coverage conditions (breadth)	Changes in cost-sharing (height)
Frequently		Australia(P,D)*, Belgium, Israel, Japan(D) , Slovak Republic(D,MD), Slovenia(D), Turkey(D)	Australia(P), Czech Republic(D), France(D,P), Luxembourg(P), Slovak Republic
Sometimes	Australia(D,P), Czech Republic(D), Greece, Japan(D,P), Luxembourg(D), Netherlands, Portugal(D), Slovak Republic(D,MD)	Chile, Czech Republic(D), Finland(D), Japan(P), Korea, Poland(P), Spain, Switzerland	Australia(D, MD), Belgium, Slovenia, Spain, Switzerland(D, MD)
Rarely or never	Belgium, Canada, Chile, Finland(D), France(P), Hungary, Iceland(D), Israel, Japan(MD), Korea, Luxembourg(P), Poland(D,MD,P), Slovenia, Sweden(D), Switzerland, United Kingdom	Australia(MD),Canada, France(MD), Greece, Hungary, Iceland, Japan(MD), Luxembourg, the Netherlands, Poland(D,MD), Portugal, Slovenia(P), Sweden, United Kingdom	Canada, Chile, Finland, Greece, Hungary, Iceland, Israel, Japan, Korea, Luxembourg(MD), Netherlands, Poland, Portugal, Switzerland(P), United Kingdom

Table 7. Current utilisation of adjustment strategies across the OECD

Note: D= Drugs, P=procedures, MD=Medical Devices, Missing info on Denmark, Norway, Spain, Turkey. * For the purpose of reducing use, changes in coverage occurs on a rarely basis. Source: 2014 OECD Health Benefit Basket Questionnaire

5.2. OECD countries sometimes use health technology re-assessment but it is not a prerequisite for adjusting the range of benefits covered

71. In order to adjust health care coverage, some countries use *health technology re-assessment*. Countries decide to initiate a health technology re-assessment for various reasons: the leading being the introduction of a new health technology, followed by the presentation of new evidence on risks and benefits of the currently covered goods and services, changes in their prices, and their patent expiry.

72. There are generally three types of re-assessment strategies: periodic and systematic re-assessment after listing; re-assessment following a specific event (for example the introduction of a new technology) and ad hoc re-assessment. Re-assessment strategies most often affect pharmaceuticals, less frequently medical devices and procedures.

73. A third of OECD countries plan a *periodic re-assessment* of the technologies included in the range of benefits covered by public funding a few years after listing. This is the case for instance in France and the Czech Republic where all coverage decisions are temporary; in Belgium for orphan drugs and in the Netherlands for expensive inpatient drugs and where coverage with evidence development agreements are signed. Australia, Chile, Finland, Japan, Korea, Poland, and Switzerland conduct a reassessments every 2-5 years of some or the whole range of benefits covered, while other countries, like Denmark, carries out reassessment of drugs on a regular basis without defining a specific time.

74. The effectiveness of systematic and periodic re-assessment has been questioned. In France, for instance, in 2014, initial conditions of pharmaceutical coverage were confirmed in 90% of cases through periodic assessment. In the Netherlands, re-assessment of expensive inpatient drugs 5 years after listing and re-assessment of orphan medicines with "covered with evidence development" after 4 years did not drive any change in coverage (Boon et al., 2015).

75. Only a few countries *initiate a re-assessment* of a technology or of a set of technologies following a specific event. Such a re-assessment can be motivated for instance by the emergence of a new technology (e.g. Australia, Chile), of new evidence on clinical safety and cost-effectiveness of existing technologies, or by a suspicion of inappropriate use revealed by utilisation reviews (e.g. Australia, Spain). In the Slovak Republic, for instance, the assessment of a new drug is automatically followed by a re-assessment of all drugs used in the treatment of the specific disease.

76. Some countries, including Austria, Belgium, France, the Netherlands and Sweden, organise *adhoc re-assessments* of some types of pharmaceutical products. The scope of ad hoc re-assessments is defined to answer to specific questions raised by professionals, payers, the public or other stakeholders. For instance, France (in 1999-2001) and Sweden (in 2002) re-assessed all medicines by therapeutic class, and ad hoc re-assessments of outpatient drugs were conducted in the Netherlands. Ad-hoc re-assessments can be initiated in Austria, Belgium and France by the reimbursement agency, the drug expert committee and/or the final decision maker (Le Polain et al., 2010). Full reviews of all medicines conducted in Sweden and in France led to delisting or changes in coverage conditions for many products. By contrast, the ad hoc re-assessments of outpatient drugs conducted in the Netherlands rarely result in delisting of drugs.

77. Determining which re-assessment strategy is the most cost-effective would require a thorough evaluation which is beyond the scope of this paper. In addition, based on the practices reported from the OECD countries, health technology re-assessment is *not always* a prerequisite for countries to adjust health care coverage.

5.3. Delisting benefits, even based on health-technology re-assessment, is difficult

78. Health technology re-assessment often drives changes in reimbursement prices or levels, changes in the set of indications or in population groups covered, or to identification of more effective treatment options and new clinical guidelines. It only scarcely leads to delisting of benefits even when results of re-assessment do not support coverage according to applicable rules.

79. In the Netherlands, for instance, where expensive inpatient drugs (often orphan drugs) have been re-assessed periodically five years after the initial positive reimbursement decision since 2006, only three negative recommendations were issued and none of the orphan drugs concerned were delisted (Boon et al., 2015). Similarly, in Australia, the Comprehensive Management framework for the Medicare Benefits Schedule (MBS) initiated in 2011 the re-assessment of 23 treatments (Hodgetts et al., 2014). Two studies recommended to delist some procedures, but all of them were not subsequently withdrawn from the range of benefits funded publicly (MSAC, 2011a; MSAC, 2011b).

80. Conversely, the re-assessment of all medicines by therapeutic class undertaken in France (in 1999-2001) and Sweden (in 2002) resulted not only in changes in guidelines but also in the delisting of drugs from the reimbursement scheme, though it took years in France to effectively delist these 800 drugs due to political pressure.

81. Providers, patients and the general public do not easily accept cuts in the range of benefits covered. Patients feel a sense of entitlement to technologies that have traditionally been covered, and easily get support from patient organisations and the media to contest disinvestments.

5.4. Explicit disinvestment strategies, with transparent criteria and stakeholders' involvement might facilitate coverage adjustments

82. A few countries have implemented explicit disinvestment strategies, with well-defined ojectives, methods and criteria. For instance, in Spain and Sweden, health technology re-assessments falls within the mandate of HTA agencies and are carried out according to clear guidelines not only at the national level

but also at the regional level as a range of health benefits covered is decided also at the decentralised level. In Australia, a review process was implemented for the Medicare Benefits Schedule (MBS) and Norway is another country which has set out a process of re-assessment, although temporarily (Box 10).

Box 10. Disinvestment strategies

In Spain, a Royal Decree of 2006 sets up a procedure for periodical review and updating of the SNS common benefits basket by including and excluding technologies from the common basket based on cost-effectiveness analysis at the national level (García-Armesto et al., 2013). The Guideline for Not Funding Technology developed by the Basque Office for HTA, sets out health technology reassessment into five phases: identification, prioritization, assessment, decision making, and action plan, with a variety of sub-steps within each phase.

The Swedish Council on Technology Assessment in Health Care (SBU) has the mandate to provide "reliable scientific information on the value of established and new technology in medicine as a basis for potential disinvestment and priority setting in health care" (Jonsson, 2009). The SBU has since its establishment in 1987 primarily focused on the identification, assessment, and prioritisation of potentially obsolete technologies in order to achieve cost savings, increase patient safety and quality of care. Assessments carried out by the SBU over the past two decades has led to changes in clinical practice for mild head trauma patients, who now are discharged rather than kept in the hospital for observation resulting in direct cost savings of 5 million USD per year. Prescription practices for depression, alcohol and drug abuse have shifted towards more effective pharmaceuticals for these disorders.

In Australia, a review process was implemented to ensure the Medicare Benefits Schedule (MBS) is contemporary, reflects current clinical practice, and directs funds to the most appropriate patient groups and services that improve health outcomes. As such, the process seeks to ensure that the Australian Government spends money in the best possible way. The review working group comprises expert clinicians in the service being reviewed. A group is established specific to each review. Review protocols for MBS are released for public consultation so all stakeholders can participate in the process as well as identify anything that may have been missed in the protocol. This is to ensure that all stakeholders can share their knowledge and perspectives on the services being reviewed, and helps to shape the outcomes.

Norway is another country which has set out a process of readjustment, although temporarily. In 2007, the Ministry of Health and Care Services has set up the Norwegian Council for Quality and Priority Setting in Health to play a key role in the Norwegian reassessment process (Mørland, et al, 2010). It was intended to combine key stakeholders, hospitals representatives, primary health care actors, patients and national authorities. The aim of this Council is to promote discussions about the health care basket based on the best evidence available. Initially the Council was established for a period of four years, but its mandate has been expanded for two additional terms. In 2015 the quality focus was removed from the mandate and the Council itself was renamed, National Council for Priority Setting in Health Care. The Council has succeeded in showing that setting priorities also means restricting (new cancer drugs, cochlear implants, mammography for 40- to 49-year-olds) coverage under a fixed budget (Mørland, et al, 2010).

83. Disinvestment strategies, however, are not always easy to implement. Key stakeholders often lack the practical tools, the dedicated resources and necessary infrastructure to conduct reviews which can build and support disinvestment policies. Moreover, stronger evidence is often necessary in order to support and justify the delisting of benefits or reduction in use of specific technologies. An important element of disinvestment strategies is to identify technologies that are candidates for assessment (Elshaug 2009; Parkinson et al. 2015). This can be done through literature reviews, searching for practices that have been debated in recent peer-reviewed publications (Elshaug et al., 2007) or through utilisation reviews revealing doubtful medical practices (Ibargoyen-Roteta et al., 2010).

84. Experiences from countries with defined disinvestment strategies and others can inform how reassessment and disinvestment strategies can be developed in other OECD countries. Already, there are several options available to countries that consider developing disinvestment strategies. First, clarifying criteria used for disinvestment may help increasing the acceptability of the process as done for making coverage decisions for new medical technologies. Second, it may be also important to involve different

stakeholders in the process of developing disinvestment strategies and setting criteria for disinvestment. Third, it seems indispensable to involve a wide range of stakeholders when making disinvestment decisions as their meaningful involvement can also help improving the acceptability of delisting. Fourth, a particular attention is needed to involve patient groups. If patients and the public are invited to adopt a "general public perspective as the funder of health care", they may understand the value of limiting access to care with little or no value with the aim to improve quality of care and contain costs (Henshall and Schuller, 2012). For patients to support disinvestment strategies, it is paramount that an open and transparent process is established.

85. Alternatively, changes in guidelines and clinical practices and effective communication about appropriate (or inappropriate) use of technologies, as seen in the *Choosing Wisely* initiative or the "do not do" lists published by NICE, might be worth considering as options to help reducing the use of low-value technologies. The 'Choosing Wisely' is led by physicians and aims to increase awareness of services for which there is strong evidence of significant over-use with potential harm or cost, and change the attitudes and practices of both doctors and patients. This campaign started in the United States, and has since been implemented in twelve other OECD countries. Case studies in Canada, France, Italy and the Netherlands also acknowledge the importance and added value of involving health professionals in developing and implementing disinvestment strategies (Henshall and Schuller, 2012) because they need to readapt their practice patterns accordingly based on the readjustment decisions.

6. The boundaries of health coverage are not uniformly defined across OECD countries

86. A wide range of interventions considered as "core medical care" are probably covered in all OECD countries because they are effective and affordable to all systems. However, doing a cross-country "item by item" comparison of these core medical care items would be impossible since positive lists include hundreds of procedures and medical goods and, by definition; "implicit benefit packages" are not entirely defined. Nevertheless, when breaking down the range of benefits covered into categories some cross-country differences are likely to appear for benefits falling into the following categories;

- Interventions whose effectiveness is low: complementary and alternative medicines (CAM) and spa treatment
- Interventions that are not cost-effective, such as high-cost medicines with low therapeutic value;
- Interventions for which risks of inappropriate use are high, such as bariatric surgery;
- Interventions which can be provided by non-physicians, such as psychological treatment;
- Interventions whose financing can in principle be left to users, such as over-the-counter (OTC) medicines, vision products, and smoking cessation products;
- Intervention whose coverage decision can be influenced by social norms, such as assisted reproductive services;
- Interventions which are at the frontier between health and aesthetics, such as breast reconstruction after mastectomy and orthodontics;
- Dental care, towards which countries have adopted different reasons, and which cannot be clustered in any other category.

87. This report will not address the question of making choices for single technologies, based on effectiveness or cost-effectiveness of single technologies any further. These processes have been thoroughly explained in sections 2, 3 and 4. Instead, the focus will now shift towards examples of health benefits whose coverage varies across OECD countries (see table 8 cross-country coverage information). Furthermore the following section aims to compare and highlight potential differences in country practices and rationale behind coverage decisions and – where possible - the consequences on access to care, use of these benefits, and health impact.

6.1. Coverage of interventions whose effectiveness is questioned

88. A minority of OECD countries has included interventions with poorly established effectiveness in their range of benefits covered (table 8). The sections below examine the coverage of complementary and alternative medicines and of spa treatments in OECD countries.

				Co	overage by	governmen	t scheme a	nd/or comp	ulsory hea	Ith insuranc	е			
Country	Coverage of interventions whose effectiveness is questioned				Coverage of interventio ns with risks of inappropri ate use	Coverage of interventio ns provided by non- physician s				Benefits whose Coverage of interventions which can be are at the frontier influenced between health and by social cosmetics		Coverage of dental care		
	Acupunct ure	Osteopat hy	Homeopat hy	Herbal medicines	Spa	Bariatric surgery	Psychoth erapy	отс	Vision products	Smoking cessation products	Assisted reproducti ve techngolo gies	Breast reconstru ction surgery after mastecto my	Orthodont ic treatment	Dental care and prosthesi s
Australia	•	۲	0	0	0	•	•	۲	0	•	•	•	0	0
Austria	۲	N/A	N/A	N/A	N/A	N/A	•	N/A	•	N/A	N/A	N/A	N/A	•
Belgium	0	0	0	0	0	•	•	0	۲	۲	•	•	•	•
Canada	0	0	0	0	0	۲	0	۲	۲	۲	۲	•	۲	۲
Chile	0	•	0	0	0	•	•	0	۲	0	۲	•	0	۲
Czech Republic	0	•	0	0	•	0	•	۲	۲	0	•	•	۲	۲
Denmark	•	N/A	N/A	0	N/A	N/A	N/A	۲	0	0	N/A	N/A	N/A	۲
Estonia	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	۲
Finland	0	0	0	0	0	۲	•	۲	0	•	۲	۲	•	•
France	•	•	•	N/A	•	•	•	•	•	۲	•	0		•
Germany	۲	N/A	N/A	N/A	N/A	N/A	-	۲	•	0	N/A	N/A	N/A	
Greece	0	N/A	0	0		N/A	N/A	0		N/A		N/A	•	
Hungary Iceland	ě	0	0	0	ŏ	ŏ	•	0	0	0				•
Ireland	N/A	N/A	N/A	N/A	N/A	N/A		N/A	ě	ě	N/A	N/A	N/A	•
Israel	O N/A	0	0	0	0	•		(N/A)	0		N/A	•	•	۲
Italy	0	N/A	N/A	N/A	N/A	N/A		N/A	•	N/A	N/A	N/A	N/A	•
Japan	۲	0	0	0	0	0		0	۲	•	0	•	•	ě
Korea	ě	0	0	0	õ	0		0	۲	ĕ	0	ŏ		
Luxembourg	ŏ	õ	ĕ	ĕ	ĕ	ĕ		ĕ	ĕ		ĕ	ĕ		ĕ
Mexico	N/A	N/A	N/A	N/A	N/A	N/A	•	N/A	0	N/A	0	N/A	N/A	۲
Netherlands	0	0	0	0	0	•	•	•	õ	•	ĕ	•	0	۲
New Zealand	N/A	N/A	N/A	N/A	N/A	N/A	Ō	N/A	•	N/A	N/A	N/A	N/A	۲
Norway	۲	0	0	0	0	•	•	0	0	0	•	•	•	۲
Poland	۲	0	0	0	۲	•	•	0	•	N/A	۲	•	۲	۲
Portugal	0	0	0	0	N/A	•	•	N/A	۲	•	•	•	N/A	۲
Slovak Republic	•	N/A	N/A	N/A	N/A	N/A	•	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Slovenia	۲	0	0	0	•	•	•	۲	•	0	•	•	•	•
Spain	0	0	0	0	0	•	0	0	0	0	•	•	0	0
Sweden	•	N/A	N/A	N/A	N/A	N/A	•	0	•	•	•	N/A	N/A	•
Switzerland	۲	0	•	•	0	•	۲	۲	۲	۲	۲	•	۲	0
Turkey	0	0	0	0	0	•	•	N/A	۲	•	•	•	•	•
United Kingdom	•	•	0	0	0	•	•	0	۲	•	•	•	•	۲
United States	0	۲	0	0	0	•	۲	0	۲	N/A	N/A	•	0	•
Notes:			For ART				reconstruct	tion						
0			Not covered											
•														
۲	Partly cove	ered	coverage c	of ART exclu	iding IVF	Varies by	region							

Table 8. Cross-country comparison of the boundaries of health care coverage

Source: 2014 OECD Health Benefit Basket Questionnaire, Health Systems in Transition, the European Observatory on Health Systems and Policies

6.1.1. Complementary and alternative medicines (CAM)

89. The role of *complementary and alternative medicine*, such as acupuncture, osteopathy, herbal medicines and homeopathy in the conventional, Western medicine is often questioned and debated. Many people are convinced that natural, herbal products are safer than prescribed pharmaceuticals, although the clinical evidence on safety and efficiency is often poor.

90. According to countries' responses, the coverage decisions (positive or negative) of CAM have never been based on HTA. Only Switzerland assessed homeopathy between 1999 and 2004. The assessment and appraisal concluded that effectiveness had not been proven, but that primary care physicians using homeopathy deliver economic care and patient satisfaction. The delisting of homeopathy in 2005 was reversed in 2011 following a popular vote. In all countries covering CAM, the prerequisite is that the treatment must be provided by a certified practitioner or a physician.

91. Acupuncture is covered in 14 OECD countries, and the form of CAM most often covered by the basic health coverage. Five of these countries cover acupuncture with certain restrictions: in Austria, Poland and Slovenia, acupuncture is only covered for pain treatment; in Germany, coverage is only granted for treatment of pain in the knees and spine; in Norway, acupuncture is covered for pain relief during labour and delivery. Osteopathy is the second most often covered CAM, included in six countries' range of benefits covered while eight countries have voluntary health insurance schemes providing coverage for osteopathy treatment. Herbal medicine and homeopathy are only covered in Luxembourg, Switzerland and the United Kingdom; in addition four countries have voluntary health insurance providing coverage with relatively high co-payments.

92. Despite discrepancies in public coverage in OECD countries, the utilisation of CAM has increased dramatically over the past decade in several countries, including Israel and the United States (Shmueli et al, 2010; Barnes et al, 2008). According to the Health System in Transition reviews produced by the European Observatory on Health Systems and Policies, the percentage of users of CAM (as reported from different surveys and for different years) was 12% in the Netherlands, the United Kingdom, Israel and Belgium, 23% in Denmark, 50% in Norway, 61% in the United States, 67% in Germany and 80% in Austria. The use of CAM is very socially marked. CAM are more used by women (in Denmark, Germany, Italy and the United Kingdom England) and by women holding a higher education and receiving higher income (Austria and Israel) (Ekholm O et al, 2006; NAO, 2005; Piel, 2007; Menniti-Ippolito and Bologna, 2004; Hofhmarcher, 2013; Shmueli and Shuval, 2004; Shmueli et al, 2010).

93. The decision to finance CAM treatments by public money is complex. The bio-medical conventional medicine refutes the medical value of CAM treatments, let alone the possibility of financing them publicly. The recognition in several countries that acupuncture might relieve pain and thus merits public finance is exceptional. Sheppard (2015) argues that the English NHS funds selected CAM treatments as a response to increasing patient demand, in spite of the lack of accepted evidence of their (cost-) effectiveness. It seems that CAM treatments will find their way into the clinical practices by conventional physicians and hospitals – which are funded by public money – by integrating them in their practices, either because of clinical belief or as a competitive advantage, facing the increasing public demand. However, countries with tight budget constraints should consider the opportunity cost of covering CAM.

6.1.2. Spa treatments

94. The evidence on the effectiveness of balneotherapy or spa therapy is fragile and weak. A recent Cochrane review concluded that the effect on symptom relief in rheumatoid arthritis was light at best, with

a low level of evidence (Verhagen et al., 2015). Another recent review of the impact on low back pain reached similar conclusions (Karagülle and Karagülle, 2015) Although some studies show that spa treatments provide slight symptom relief in patients suffering from musculoskeletal conditions, cost-effectiveness estimates reveal overall less convincing results (Ziljstra et al 2007, Guidelli et al 2012, Cozzi et al, 2015).

95. Only six OECD countries report to cover, at least partially, the costs of spa treatment: Czech Republic, France, Greece, Hungary, Luxembourg, Poland and Slovenia.

96. Countries covering balneo or spa therapy have not conducted evaluation. In these countries, coverage decisions might have been partly influenced by the fact that these therapies address conditions with a high burden of disease and no available cure, and increase patients' well-being without any adverse effect. Moreover, rationale for coverage may be due to long tradition of prescribing and using spa treatment in some Eastern European countries.

6.2. Coverage of interventions with risks of inappropriate use – the example of bariatric surgery

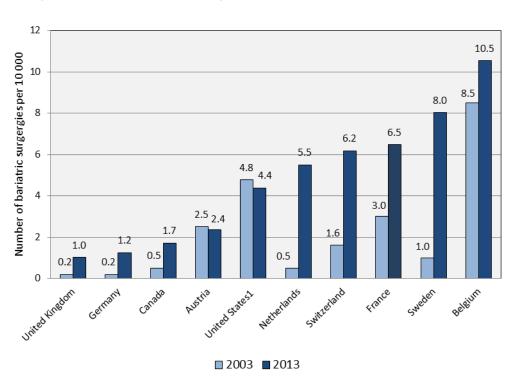
97. Morbid obesity has increasingly become an important health problem worldwide and those with a Body Mass Index (BMI) greater than 30kg/m² are at significantly higher risk of developing diabetes, cardiovascular disease, depression, disability and overall decreased life expectancy. According to OECD Health Statistics 19% of the adult population is obese across the region, with the United States and Mexico having the highest prevalence of obesity (35.3% vs 32.4%) and Japan, Korea the lowest (3.7% vs 4.7%). Conservative approaches such as dietary, behavioural and pharmaceutical treatments are available, but these often fail to show long-term effects on weight loss (Maggard et al 2005, Sjostrom et al 2004). Therefore, bariatric surgery has become a preferred treatment for obesity and related clinical comorbidities (O'Brien et al 2013).

98. Bariatric surgery is *only* effective for patients above a certain BMI level and/or accompanied by other risk-factors. While bariatric surgery often is included in the range of benefits covered, its coverage is *always* associated with clinical conditions. The general clinical criteria are defined as the patient being at least 18 years of age, BMI >40kg/m², or >35kg/m², in addition to being diagnosed with one or more comorbidities. In countries with lose control of compliance with these requirements; there is a risk of over-use, which affects the benefit-risk ratio of the procedure. As with all surgical interventions, perioperative, surgical, nutritional and psychological complications may arise following a bariatric surgery. Moreover, recent research suggests that those having undergone bariatric surgery are at higher risk for suicide (Tindle et al 2010).

99. Twenty countries include bariatric surgery as part of their range of benefits covered when patients are found eligible according to a set of clinical criteria. Out of all the countries for which information was obtained, only three counties report to not having included bariatric surgery as part of the range of benefits covered (Czech Republic, Iceland, and Korea (under discussion)). Bariatric surgery was found cost-effective for the countries that carried out an HTA prior to inclusion in the range of benefit covered (Australia, Chile, Korea, Slovenia and United Kingdom). Following more than 6 years under a CED scheme, Switzerland modified the criteria to only allow Competence Centres to perform bariatric surgery in order to apply a strict patient selection. In the Netherlands, the HTA concluded that scientific evidence did not support bariatric surgery for patients with BMI<35kg/m² and diagnosed with diabetes mellitus type2. In France, Germany Israel, Norway, the Netherlands, Switzerland, the United Kingdom and the United States, bariatric surgery is only covered when conservative approaches, such as lifestyle interventions, have been found ineffective. The same countries, in addition to Belgium, Luxembourg and Turkey, require that the decision to perform the surgery must be made by a multidisciplinary team consisting of a psychologist, an endocrinologist, a nutritionist, and a surgeon.

100. The utilisation of bariatric surgeries has tripled in some OECD countries between 2003 and 2013. Belgium performed the highest number of bariatric surgeries in 2013 (10.5 per /10 000 population, whereas Sweden has seen the largest increase between 2003 and 2013 (1.0 to 8.0 per /10 000 population). France performed 6.5 surgeries per /10 000 population, which is six times or more than Germany, United Kingdom and the United States (Figure 5). The majority of the patients undergoing surgery in France were female (82%) with a mean age of 40 years old, and 68% of those who underwent bariatric surgery in 2013 were severely obese with a BMI between over 40 kg/m² (CNAMTS, 2015).

101. The coverage conditions related to clinical and procedural aspects do not seem to affect the utilisation of bariatric surgery. For example, Belgium with quite strict conditions for coverage has the highest number of performed bariatric surgeries per 10 000 / population in 2013. Similar trends can be identified for aforementioned countries such as France, the Netherlands, Switzerland and the United Kingdom, that all have implemented coverage conditions related to clinical safety, but all see a significant increase in number of surgeries performed over the past decade. Conversely, United States with the highest prevalence of obesity in the OECD performed fewer surgeries in 2013 than in 2003. Fewer patients are undergoing bariatric surgeries in the United States compared to countries such as Belgium and Sweden.





Source: Note: 1 = 2011 data from Buchwald & Oien, Metabolic/bariatric Surgery worldwide 2011, Obesity surgery, 2013. Source: (CNAMTS, 2015)

6.3. Coverage of interventions provided by non-physicians - the case of psychological therapy

102. The medical profession has traditionally played an important role in health systems, by contributing to setting standards for care and delineating the scope of practice of other health professionals (Freidson, 1984).

103. Psychological therapies are considered cost-effective if provided by adequately trained professionals in appropriate settings, with the intensity and length of interventions which are tailored to the level of complexities of individual patients with mental illness. Psychotherapy may also lead to savings in other medical and societal costs and are at least as effective as antidepressants (Lazar S. 2014; NICE, 2009; Bedi et al., 2000). Individuals prefer psychological or talking therapies to medication when they are given the choice (OECD, 2014).

104. The majority of OECD countries, with the notable exceptions of Estonia, Hungary, New Zealand and Spain, cover psychological therapy without conditions, significantly limiting access to care. When searching medical help for mental health problems, the primary care physician and not a mental health professional is often the first encounter with the health system, either as point-of-referral or as provider of the treatment itself. Evidently, the psychological treatment included in the range of benefits covered mainly takes place in the public, primary healthcare system.

105. To take advantage of this crucial role of the primary care physician in the provision of mental health care, a number of countries have established primary care-based programmes of cognitive behaviour therapy (CBT), delivered by general practitioners. In Norway, for example, primary care physicians can provide and be paid for practicing CBT. To support the CBTs, online therapy options are available in Australia, New Zealand and the United Kingdom. This easily accessible online therapy tool is a way of improving the efficacy and quality of the care provided by the primary care physician. Furthermore, introducing primary care-based CBT or talking-therapy equivalents is likely to be cost-saving relative to introducing stand-alone programmes, increasing reimbursements of non-primary care practitioner provided therapies (especially where alternative practitioners are private), or investing in capacity building for the delivery of psychological therapies.

106. Although coverage conditions do not limit the access to mental health care, some countries face access challenged due to stigma, shortage of providers and service availability. This is seen in Poland, despite the limitless number of therapy sessions being covered, access is still a pressing problem. Also the availability of community mental health services for people with severe mental illness varies across the OECD countries. While a number of countries offer a wide range of crisis, early intervention, outreach, recovery and day services, these are limited in some countries. Czech Republic, Estonia and France report that comprehensive community-based services are not routinely available.

107. Some countries have implemented specific coverage conditions of psychological therapy sessions. In France, treatment is covered as long as provided by psychiatrists, and in Switzerland the psychologist providing the therapy must be employed by a private psychiatrist. Israel and the Netherlands have limited coverage to a specific number of sessions, equal to 10 hours and 5 sessions respectively. Different conditions are in some cases applied for children and adolescents, as seen for example in Finland where all psychological therapy is provided for free. In recent years, countries have been expanding services available in mental health. Although the psychological therapies are not included in the range of benefits covered in Spain, mental health care services and rehabilitation have been expanded and community-based services have been included. Also research and technological developments have contributed to an expansion of treatment options available for mental illness. Computer-based psychological therapy has been piloted and found to be cost-effective and to produce positive clinical outcomes in some countries. It may be revolutionary in treating mental illness as well as improve access to treatment (Cuijpers et al 2009).

6.4. Coverage of interventions which can potentially be financed by patients

108. For a range of interventions (OTC medicines, vision products and smoking cessation products), OECD countries have adopted different approaches. While some provide partial or full coverage, others

consider that in most cases, consumers can pay the bill. Tinghog (2010) lists 5 conditions to be fulfilled by a type of health intervention to justify its financing by users in most situations (see box 8). The paragraphs below analyse the coverage of OTC medicines, smoking cessation products and vision products in OECD countries, as well as implication of their use.

Box 11. Conditions to be fulfilled to leave the financing of a health good or service to patients

Tinghog (2010) suggests 5 conditions to assess whether the financing of a specific health good or service can be left to patients' responsibility.

- 1. The considered health-care service should enable individuals to value the need and quality both before and after utilisation (consumption).
- 2. The considered health-care service should be directed towards individuals with a reasonable level of individual autonomy, able to make informed and rationale consumption decisions.
- 3. The considered health-care service should be associated with low levels of positive externalities, so that non-consumption does not endanger others;
- 4. The considered health-care service should be associated with a demand of sufficient magnitude to generate a private market.
- 5. The considered health-care service should be associated with payments affordable for most individuals.

Source : Tinghog (2010)

6.4.1. Over-the-counter medicines

109. A majority of countries do not cover over-the-counter (OTC) medicines. A few countries cover a small number of OTC medicines, included in a positive list (e.g. Australia, the Netherlands) and sometimes only for patients with specific conditions (e.g. Denmark and Germany). A few countries cover a wider range of OTC medicines, provided that they are included in a positive list and prescribed by a physician (e.g. France, Switzerland).

110. No study has analysed the consequences of covering or not covering OTC medicines on access, costs or health. A few studies have analysed the consequences of *delisting* OTC drugs on expenditure, prescription patterns and prices. In France, delisting of OTC drugs with low therapeutic value took place between 2002 and 2011. Following the delisting of some medicines in 2006 and 2008, the prices of delisted OTC medicines increased by about 43% on average, with wide variations in price changes, ranging from 25% decrease to 249% increase. In at least one case (delisting of expectorants), it led to an increase in the prescription of reimbursed drugs (antitussive drugs), reducing by half savings for social health insurance and raising questions on the appropriateness of care (Pichetti and Sermet, 2011). In the Czech Republic, in 2012, about 95% of OTC medicines became non-reimbursable and this contributed to savings of EUR 21.6 million in the public fund while it did not lead to an increase of the average price of OTC drugs (Chytilová and Šebesta, 2015).

6.4.2. Vision products

111. Vision products include a wide range of more or less complex products, ranging from simple standardised reading glasses to multi-focal and progressive glasses and contact lenses. While standardised reading glasses can be found in a many retail outlets and purchased without prescription, more complex products need to be adapted to correction needs. This requires an eye examination by a health professional

(ophthalmologist or optometrist). Innovation in vision care constantly creates new products, such as glasses with thinner or transitional lenses, as well as polarized, anti-reflective coating and aspheric contact lenses (Consumer Affairs, 2015).

112. The large variety of products, combined with differences in national market regulations and competition, results in wide price variations. While standardised reading glasses can be found at very low prices, more sophisticated products can cost up to USD 400 or more in the United States (Kircheimer, 2013). In 2007, optical shops' average turnover per client amounted to EUR 110 in Germany and EUR 188 in the United Kingdom, the difference being mostly explained by the prices of contact lenses (Martimort and Pouyet, 2013).

113. The prevalence of vision problems varies in OECD countries: 74% of people in the United Kingdom wear corrective eyewear or have had laser eye surgery, while in the Netherlands more than 6 out of 10 people wear eye glasses or contact lenses (Britain's Eye Health in Focus, 2013; Bruggink, 2013).

114. A number of arguments can justify the non-coverage of vision products. Vision products fulfil the conditions by Tinghog (2010 – see box 11): consumers can relatively easily detect vision problems and assess the correction provided by vision products, such as eye glasses and/or contact lenses; the level of externalities of the non-consumption of vision products is rather low (except for drivers); the demand is high enough to generate a private market; the costs of vision products are affordable to most individuals; and finally, most adults have a sufficient level of autonomy to make informed choices. In addition, in some contexts, health insurance can provide incentives for providers to charge high prices and for patients chose more expensive products. In France, where private (complementary) health insurance pays more than 71% of the bill, consumers and sellers have adopted opportunistic behaviours: sellers tend to offer vision products at a price that matches the level of coverage, a practice known as "bill optimisation". Consumers do not seek to obtain low prices since they have the illusion to get "free vision products" (Martimort and Pouyet, 2013).

115. On the other hand, providing medical care to those with uncorrected refractive disorder is medically necessary. Uncorrected refractive disorders cause many problems for people including, "loss of independence and mobility, difficulty with everyday activities, increased risk for falls, depression, motor vehicle collisions, and social isolation" (Ya-Ping 2013). For children, it may hinder reading and learning in school (Chiu-Fang 2013). Access to and use of eye care is unequal and inequalities, though not totally explained by coverage, may be accentuated by lack of coverage. In the United States, for instance, the frequency of eye examination for people over 40 years with visual impairment varies according to race and ethnicity, income, and education, within the country and within each state (Chou 2012).

116. In two third of OECD countries, eyeglasses and contact lenses are not included in the range of benefits covered (see table 9).

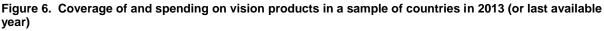
	Working-age adults, no specific entitlements	Other population groups
Partly and mostly covered/financed by basic health coverage	AUT, CHL, GRC, IRL, LUX, PLN, SWE	BEL (children, seniors, high impairment); NOR (people with disability); CHE (children).
Partly and mostly covered/financed by <u>secondary</u> private health insurance	FRA, SVN	
Mostly not covered	AUS, BEL,CAN, CHE, CZE, DNK, FIN, GER, ISL, ISR, ITA, JPN, KOR, MEX, NLD, NZE, NOR, PRT, GBR	

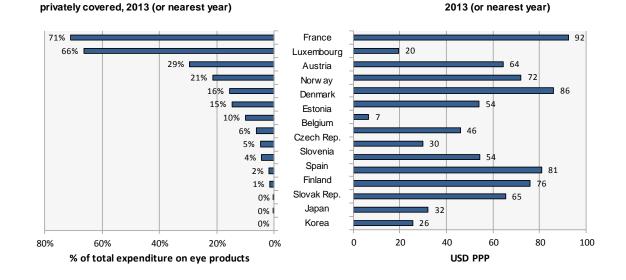
Table 9. Coverage of vision products in OECD countries

Source: Notes: (1) In Chile, people publicly insured with a restricted choice of public providers are covered, others are generally not); (2) In France, basic health coverage also covers a substantial share of spending for dental care. Sources: Authors' estimates based on data from the Health Systems Characteristics Survey, 2012 and the System of health accounts, 2014

117. There is no obvious link between coverage of vision products and spending on vision products at the macro-economic level, but information on appropriate access to eye care and products is lacking. In OECD countries for which data are available, the overall coverage rate of vision products is not linked to the level of per capita spending (see Figure 6). Spending per capita, however, results from three components: quantity and quality of products used, and price paid. The extent to which all people in need of correction of refraction error access eye examination and wear glasses or lenses is not known. In the decentralised Canadian health system, the lack of a centralised policy on eye health care coverage has resulted in the prevalence of avoidable vision impairment or loss disparately affecting the population, in particular the elderly, across the country. While some provincial and territorial governments cover annual routine eye examinations, other have user fees which may be regarded as a barrier to access eye care affecting those not covered by employer-subsidized supplemental health benefits or those with low income. Compared with adults with mid- to high income living in government-insured provinces, those residing in provinces with no annual insurance were associated with 50% higher odds of having vision problems if their income was less than midlevel, and 30% lower likelihood if their income was midlevel or higher (Ya-Ping 2013).

Expenditure on vision products per capita,





Source: OECD Health Statistics. 2015.

6.4.3. Smoking cessations products

Share of expenditure on vision products publicly or

Smoking is one of the most harmful behaviours to human health, and causal links have been well 118. established between smoking and severe morbidity and mortality. Smoking cessation is along with childhood immunisation and aspirin use among high-risk populations the most cost-effective and clinically valuable preventive measures available and countries should be encouraged to grant public coverage for these services (Maciosek et al 2006). The efforts invested in encouraging smokers to quit have contributed to a substantial decrease in the number of smokers over the past decade. The proportion of adult smokers in the OECD countries has decreased by one fifth between 2000 and 2013. The steepest decrease was seen for Denmark, Iceland, and Norway, all having a decrease of more than 40% (OECD, 2015a).

Smoking cessation treatment can be provided by pharmacotherapy most commonly in the form of 119. Varenicline and Bupropion; as well as nicotine replacement products such as nicotine patches or chewing gums. This treatment is often accompanied by individual or group counselling provided by primary care physician or other authorised healthcare personnel. The use of assistance in quitting smoking has grown increasingly common, and those using assistance are associated with greater success rates than those who do not (15.2% vs 7.0%) (Zhu et al 2000).

120. Despite the convincing cost-effectiveness data and success rates, there are discrepancies in coverage of smoking cessation treatments across the OECD countries. Smoking cessation programs are covered in half of the 34 OECD countries, however the conditions and/or restriction of coverage and the type of smoking cessation treatments covered vary between countries. In most countries where smoking cessation programs are covered, it mainly concerns coverage of specified quantities of Varenicline or Bupropion prescribed by primary care physicians. This is the case in Belgium, for example, where Varenicline and Bupropion are covered after one pack, or in the case of suffering from chronic obstructive pulmonary disease (COPD), and partly covered when prescribed in large quantities. Prescription drugs are

more often covered than NRTs, except for in France where the target population for coverage is defined (pregnant women, COPD patients or young people). In some cases, the participation in support groups or therapy is a prerequisite for receiving smoking cessation coverage, such as in Israel, the Netherlands and Sweden. In Australia, Belgium and Switzerland, the basic coverage of smoking cessation treatment can be supplemented by private insurance.

121. The decision-making process for coverage of smoking cessation treatments is usually based on HTA (Australia, Belgium, Chile, Finland, Hungary, Israel, the Netherlands, Sweden, Switzerland, and the United Kingdom). Hungary was the only country to reject the inclusion of smoking cessation products, based on high budget impact and the fear to see other life-style related products to apply for public coverage.

122. It is worth noticing, however, that some of the countries having experienced the steepest decrease in smoking prevalence over the past decade do not cover smoking cessation products (Denmark, Iceland, Norway). Some studies point out that a large majority of former smokers managed to quit unassisted (Chapman et al 2010, Zhu et al 2000), and suggest further that public resources should rather be dedicated to anti-tobacco policies, tobacco-free public spaces and mass media campaigns. A large evidence-base also confirms that the use of mass media campaigns is a powerful tool in reducing the prevalence of smoking, because it succeeds in reaching out to the population as a whole (Sims et al 2014, Langley et al 2012).

6.5. Intervention whose coverage decision can be influenced by social norms; assisted reproductive technology

123. Assisted Reproductive Technology (ART) is a set of treatment methods allowing people to achieve pregnancy in cases where male and/or female infertility or other reproductive challenges have been diagnosed. While the average age of first-time mothers have increased steadily over the past decades as well as changes in women's labour market conditions in many OECD countries, ARTs have also provided women with the opportunity to have children later in life. Infertility is multi-causal and can concern both men and women, and one in eight couples are affected (Center for Disease Control). Depending on the clinical context, ART can be provided in the form of fertility medications, which mainly stimulate to the development of follicles in the ovaries, artificial insemination and the more complex in vitro fertilisation (IVF).

124. Despite the positive effects ARTs have had for many people with fertility challenges, the literature shows that there is clear evidence of limited effectiveness of ART with increasing maternal age. For instance, in Australia in 2003, the success of fresh, non-donor (oocytes/embryos) treatment cycles varied by women's age. Women aged 25–29 years achieved the greatest success, with 27.5 % of initiated cycles achieving a live delivery. Women aged 40–44 years had a success rate of 6.4 %. (Macaldowie et al, 2012). When women aged 40 years who require ART receive a donor-egg, on the other hand, almost all of these women are able to become mothers (Sobotka, 2013).

125. How countries cover ART also depends on the type of treatment. For example, the conservative medical fertility treatment is included in range of benefits covered in the vast majority of OECD countries. IVF, however, is covered in all countries except four of the responding countries (Japan, Korea (under discussion), Poland and Switzerland). The remainder OECD countries have defined the coverage conditions mainly along the lines of clinical effectiveness, with the maternal age and number of covered cycles as the leading criteria. For example, Chile and Czech Republic only cover IVF until the maximum maternal age of 37 and 39 years respectively, whereas France and the Netherlands have extended coverage until maternal age of 43 years and Greece to the maternal age of 50 years. In Europe, Belgium covers the highest number of cycles, equal to six, while the majority of countries cover three (Denmark, Germany,

Netherlands and Spain). Two countries have also defined upper age limit criteria for men (Austria and Germany).

126. Making informed IVF coverage decisions is challenged by limited and poor quality cost-utility and cost-effectiveness data, implying that coverage decisions in some countries are founded on alternative rationales taking into account clinical, ethical and societal considerations (Mladovsky et al, 2010). The definition of infertility as a clinical condition or the coverage of IVF as serving a medical need, guided decisions on both exclusion and inclusion in the range of benefits covered in several countries (United Kingdom, United States). Nevertheless, this rationale excludes those whose infertility is caused by non-clinical reasons, such as lesbian couples and those suffering from "unexplainable infertility". Rationales embedding equity of access to care would in addition include those falling outside of the clinical decision-rationale, as long as the IVF treatment and funding are provided publicly. Societal aspects may argue for coverage in order to increase a country's total fertility rates. A RAND study estimated that if the United Kingdom applied similar coverage conditions and utilisation of ART as Denmark, the fertility rate in the United Kingdom would increase from 1.64 to 1.68. (Grant et al 2006).

127. As one can expect, the utilisation rates of IVF across Europe are closely connected to coverage policies in the respective countries. In countries were the coverage policies are stricter formulated, the utilisation rates are significantly lower. Countries with liberal policies, for example where IVF eligibility criteria have been extended to also concern lesbian couples, like Sweden, have twice as many cycles per million as countries with more conservative policies, such as Italy and Portugal where only heterosexual married couples are eligible for coverage (Silva et al 2012). Austria, that previously had restrictive access criteria, changed their constitution as of the 1st of January 2015 to allow lesbian couples living in civil union receiving IVF treatment (Legal Information System of the Republic of Austria).

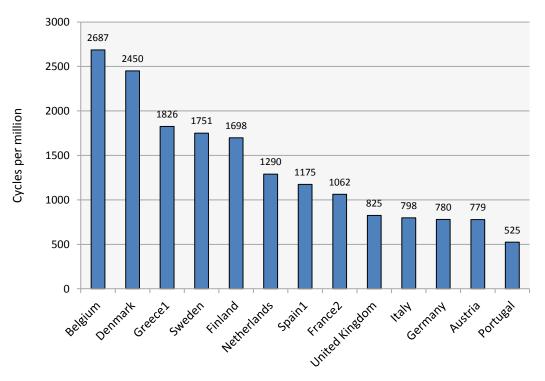


Figure 7. Utilisation of IVF in Europe

Source: Berg et al 2012 Note: 1= data from International Committee for Monitoring Assisted Reproductive Technology, 2003 2= data from European IVF-Monitoring Consortium, 2007

128. Coverage policies of IVF using donor gametes and donor embryos also vary across OECD countries. Utilisation of donor gametes/embryos is sometimes found to be controversial because it is considered to be balancing on a thin ethical line (Brezina et al, 2012). Berg et al. (2012) looked at the coverage and practices of IVF in eleven European countries⁵, which highlighted that IVF using gametes is covered across all the selected countries with the exception of Austria and Italy (with coverage restricted to semen only in Germany). When the IVF includes donor embryos, it is subject to stricter regulations. In addition to Austria and Italy, three other countries do not provide coverage for procedures involving donor embryos; Denmark, Germany, and Sweden (Table 10). The reasoning in Denmark and Sweden is based on the perception that the child should have a genetic link to at least one of the parents (Berg et al, 2012).

Table 10. Coverage of donor gametes and embryos

	Donor gametes (semen, oocytes)	Donor embryos
Yes	BEL, DNK, FIN, FRA, GER ¹ , GRC, NDL, PRT, ESP, SWE, GBR	BEL, FIN, FRA, GRC, NDL, PRT, ESP, GBR
No	AUT, ITA	AUT,DNK, GER, ITA, SWE

Note: 1= only semen. Source: Berg et al 2012

6.6. Coverage of interventions which are at the frontier between health and cosmetics

129. A few treatments stand at the frontier between health and aesthetics. Cosmetic surgery is generally not covered. However, in some cases, reconstructive or plastic surgery is not considered to be "cosmetic" and is potentially covered (e.g., surgery to correct the result of injury, post-mastectomy breast reconstruction, surgery needed to treat certain congenital defects such as cleft lip or cleft palate). OECD countries practices related to breast reconstruction are not homogenous. Orthodontic treatment is another example where the frontier between medical necessity and cosmetic goals is blurred – as least from a lay perspective.

6.6.1. Breast reconstruction

130. Bilateral and contralateral mastectomy may be provided as part of cancer treatment and it is also increasingly used as preventive care among high risk women with family history and/or disease-causing mutation of BRCA1/BRCA2 in recent years.

131. After mastectomy, breast reconstruction surgery can be provided to women to rebuild the shape and look of the removed breast and OECD countries generally provide breast reconstruction surgery as an integral part of breast cancer treatment. Although specific types of implants and necessary conditions vary across countries, this procedure is covered publicly for patients in most countries with the exception of Korea. But preventive risk-reducing mastectomy and subsequent breast reconstruction procedures are covered only in some health systems (e.g., in the United States depending on the insurance contract).

132. HTA has not been generally conducted to evaluate breast reconstruction across countries. But few years ago, an American study comparing five methods of breast reconstruction surgery found the use of autologous tissues was cost-effective while implant-based techniques were not (Grover et al., 2013). The Netherlands will collect data in the coming years to test the degree of cost-saving in relation to the use of autologous fat transplantation techniques which was approved for a conditional coverage in 2015 over the insertion of breast prostheses which has been traditionally covered in the country.

⁵ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Portugal, Spain, Sweden, United Kingdom.

6.6.2. Orthodontic treatments

133. Orthodontic treatment aims to correct the position of crowded or crooked teeth and prevent further damage on teeth or abnormal development of teeth and jaw. Twelve OECD countries partially cover orthodontic treatments (Belgium, Czech Republic, Finland, France, Greece, Hungary, Iceland, Japan, Luxembourg, Norway, Poland, Switzerland, Turkey and the United Kingdom). Coverage is most often limited to children with age varying age limits: 9 in Belgium, 12 in Poland, 16 in France, 18 in Finland and Luxembourg and 20 in Norway. In Hungary, coverage is restricted to medical conditions, such as facial malformation, cancer or trauma), while in Japan it is limited to serious cases needing surgery. In Canada, orthodontic treatments are only covered in some provinces and by some private health insurance plans.

6.7. Coverage of dental care

134. Dental services are not systematically included in the range of benefits covered in OECD countries, though oral health is known to be an important aspect of health. In 18 OECD countries, basic health coverage includes dental care but patients usually have to pay a share of the cost (see Table 11 below and OECD, 2016). In three OECD countries, dental care is mostly funded by private health insurance, which complements basic coverage (France) or covers benefits which are not covered by basic health coverage (Canada and the Netherlands). In other OECD countries, dental services are essentially not covered. In Denmark and Norway, however, where dental services are generally not covered for adults, the share of public spending in total is higher than 20% suggesting that some population are covered. The levels of coverage are the lowest in Spain, Mexico, Israel, and Switzerland (see OECD 2016 and Table 11 below).

Type of coverage	Countries
Partly and mostly covered/financed by basic health coverage	Australia (care), Belgium, Chile (1) (public/public; <6yr and >60yr), Czech Republic, Finland, Germany, Greece, Hungary, Ireland, Japan, Luxembourg, New Zealand (<18), Poland, Slovak Republic, Slovenia, Sweden, United Kingdom, United States
Partly and mostly covered/financed by secondary private health insurance	Canada, France (2), Netherlands
Mostly not covered	Australia (Prostheses), Chile (1) (pub/priv and private), Denmark, Estonia, Iceland, Israel, Italy, Korea, Mexico, New Zealand (adults), Norway, Portugal, Spain, Switzerland.

Table 11. Coverage of dental care and prostheses in OECD countries

Source: Notes: (1) In Chile, people publicly insured with a restricted choice of public providers are covered, others are generally not); (2) In France, basic health coverage also covers a substantial share of spending for dental care. Sources: Authors' estimates based on data from the Health Systems Characteristics Survey, 2012 and the System of health accounts, 2014

135. The links between coverage and use of dental services and oral health are complex. At macroeconomic level, there is no link between the level of coverage (public or private) and per capita spending for dental services (see Figure 8). At the micro-level, Manski et al. (2015) observed that dental attendance⁶ among adults over 50 was the highest (above 72%) in Sweden, Denmark and Switzerland in 2006-2007 and the lowest in Southern European countries and Poland (less than 36%). Here again, the link between coverage entitlements and use of dental services is not obvious.

⁶ Use of dental services in the past year.

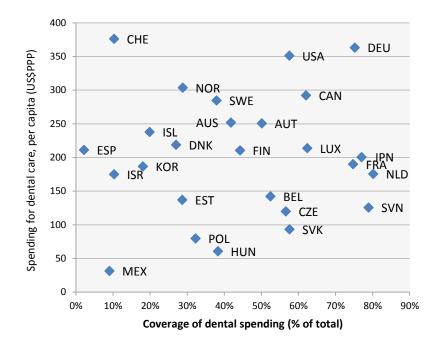


Figure 8. Coverage of dental services and spending per capita, 2013 (or nearest year)

Source: System of health accounts, 2015

136. Socio-economic inequalities in oral health and use of dental services have been widely documented. Unmet needs for dental examination tend to be more frequent on average in countries were dental services are mostly not covered (e.g. Portugal, Iceland, Italy, Estonia, Spain) and also tend to be more influenced by income (see OECD, 2015c). Inequalities are particularly observed on preventive services. In Canada, income-related inequity in preventive dental care utilization is three times larger than what is measured for specialist services utilization (Grignon et al., 2010).

137. However, low attendance to dental services is not only explained by unaffordability. Using data from the 3rd wave of the Survey of Health, Ageing and Retirement in Europe (SHARELIFE), Listl et al. analysed non-attendance to dental services throughout the lifetime in older adults. Life-time non - attendance varies across European countries, ranging from 4.6% in Sweden and 9.5% in Denmark to more than 50% in Greece, Italy, Poland and Spain. The lack of self-perceived need is the most frequent reason quoted by respondents for non-attendance in 10 out of 13 countries. In only three countries (Denmark, Spain and Switzerland) more than one quarter of respondents reported unaffordability as a reason for non-attendance.

138. Finally, no available data allow us to make any conclusion between public coverage of dental care and dental health. Only few indicators are available at national level, only in a few countries. In children, the mean Decayed, Missing, or Filled Teeth (DMFT) score in 12-year old children, has been widely used. In Europe, the DMFT score has steadily decreased in the last decades but inequalities remain across OECD countries for which these data are available (see Figure 9). Again, the link between oral health in children and coverage is not obvious. In older people, oral health can be assessed by chewing ability, dental wearing and edentulousness, but this indicator cannot be used to assess current coverage practices.

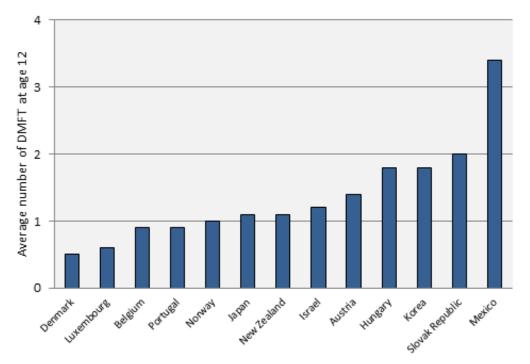


Figure 9. Average number of Decayed-missing-filled teeth (DMFT) in children at 12

6.8. The reasons why certain benefits are or not covered cannot be linked to countries' income or explicit coverage criteria

139. Cross-countries differences in the range of benefits covered are explained by many factors that go beyond or even sometimes bypass current decision-making processes. Discrepancies are not explained either by country's level of income, health spending nor public health spending per capita – the hypothesis here being that rich countries could afford a more "generous" level of coverage.

140. First, countries differ in their approach of what deserves public funding and what can be left to the financial responsibility of users, as seen for dental care and vision products, or for OTC medicines. Though these categories include goods and services whose effectiveness – and sometimes cost-effectiveness - could not be contested, they are not uniformly publicly covered. While some countries recently delisted some of these categories, in most cases, coverage or non-coverage (for the whole category, independently of the coverage of individual goods and services) does not seem to be further questioned. Path-dependency seems to explain the status quo. Actually, countries have to trade off the opportunity costs of public coverage against the societal cost of unmet medical needs (in terms of burden of disease but also in terms of equity in access to care). The analysis of dental care coverage and use suggests that first, attendance to dental services is not directly linked to coverage of dental care, and second, inequalities in unmet need exist even in countries with coverage, albeit to a lesser degree. Beyond coverage, countries should probably focus on policies aiming to promote oral health, preventive care and access for vulnerable people.

141. Second, in some cases (e.g. homeopathy), authorities are aware that treatments may not be clinically effective, but continue to fund them to respond to patients' demand. The fact that these treatments are relatively cheap and increase patients' satisfaction and well-being without raising safety issues often tip the scales in favour of continuing coverage in countries where these therapies have traditionally been covered. The assumption here is that the opportunity costs are small.

142. In other cases, cross-country differences might be explained by social norms (e.g. restrictions on ART methods or target population such as marital status or gender of parents) or just the timing of this study (e.g the coverage of breast reconstruction after mastectomy is under consideration in countries where it is not yet covered).

143. While coverage of these "non-core" activities by private voluntary health insurance is often an option, it is currently questioned in Australia, where private health insurance is publicly subsidised, especially for CAM whose effectiveness is questioned.

7. Adjustments of the range of benefits covered face a number of challenges that are expected to last

144. Countries face a number of challenges when updating the range of benefits covered. The first one relates to **timing**. There is obviously a trade-off between quick access to innovative treatments and the necessity to support decision-making based on sufficient and strong evidence of clinical effectiveness, comparative effectiveness and, where relevant, cost-effectiveness.

145. The time required to make coverage decisions for new medical technologies varies across countries and across technologies, but typically takes several months. Member countries of the European Union are in theory bound to a time limit of 180 days for the whole process from application to coverage (and often pricing) decision for medicines based on a Transparency Directive adopted in 1989, but this deadline is not systematically met and such a deadline does not exist for other technologies. For example, coverage decisions for pharmaceuticals are usually made between 1 and 2 months in Denmark, but in the Netherlands, on average, it takes between 1 month and 9 months between application submission and coverage decisions, depending on the discussion about effectiveness, cost-effectiveness and the negotiation of the Minister. Some of these countries have adopted shorter time frame (e.g. Czech Republic) and many of them have shorter time frame for generics. The time needed to make coverage decisions varies across OECD countries also for other medical technologies. For example, it is less than 3 months for all types of medical technologies in Hungary but it takes up to two years in Turkey. Typically, the time required for coverage decisions is shorter for medicines than for medical procedures and medical devices.

146. While most countries assess new technologies when they appear and make separate decisions throughout the year, a few countries –like Israel and Chile- make all decisions for all technologies once a year, with the constraint to comply with a given budget. This potentially imposes longer delays for access to innovative treatments but on the other side, highlights opportunity costs of accepting every new technology. Nonetheless, in Chile, coverage decisions usually take about 2 and 3 years after the application submission.

147. Setting time limits may help to adjust the resources needed to comply with the time frame. Giving priority to making assessment and coverage decisions for treatments with very high expected value is also an option to guarantee timely access to very innovative treatments.

148. **The second challenge relates to the costs and benefits of HTA.** Performing HTA entails costs that should not exceed its benefits. One way to reduce HTA costs is to perform a unique assessment for different jurisdictions in order to avoid duplication of efforts as done through the Australia New Zealand Therapeutic Products Authority for regulation of market entry. Another way is to facilitate bilateral collaborations to exchange knowledge on HTA methodology and practice, which was seen between for example the Polish and French HTA agencies. International collaborations could also contribute to increased data availability, improved practicability and more timely access to new technologies. In the European Union, the European network for Health Technology Assessment (EUnetHTA) has been working on cooperation and harmonisation of HTA across member countries. Data from other countries are also used as important source of information in some countries as they are not always available in the

country-specific context. For example, Luxembourg is part of the European network for Health Technology Assessment (EUnetHTA), and HTA results from other countries have been used to inform coverage decisions in the country.

149. The third one relates to **the evidence available to support assessment and coverage decisions**. At the time of assessment, the evidence available is often limited, and typically scarcer for procedures (not subject to "marketing authorisation") than for medicines (section 4.2). The lack of evidence at the time of assessment is expected to increase further while the concept of "real-world evidence" is gaining traction, and several OECD countries try to resolve this challenge by allowing access to certain medical technologies under the condition of monitoring their effectiveness in real life.

150. When doubts exist about the effectiveness of a new technology, countries have developed managed entry agreements (MEAs). MEAs take several forms, including "coverage with evidence development", where the new technology is temporarily covered under the condition that information on effectiveness in real life will be collected. For medicines, they also take the form of "performance-based agreements", linking the price paid to performance of the product observed in real life. MEAs have been increasingly used, especially in European countries such as Italy and the United Kingdom, but a thorough assessment of their impact is needed. They undoubtedly offer quicker access to new technologies but coverage decisions are difficult to reverse even when cost-effectiveness is not confirmed. In addition, performance-based agreements are suspected to impose an administrative burden to payers and to provide limited returns to payers.

151. Adaptive licensing is currently experimented by several medicine agencies (e.g. in Europe). It aims to provide quicker access to promising medicines treating severe unmet medical needs, with a lower level of evidence collected in clinical trials and then to assess the effectiveness of the product throughout its life-cycle (OECD, 2013; Eichler et al., 2015). This actually coincides with the development of information systems which have the potential to enable continuous monitoring of health care pathways and related outcomes. While these potentialities offer great perspectives for HTA experts, they also require new methods and processes, which could help to update the range of benefits covered.

152. A fourth challenge ahead is **the emergence of new technologies** which combine several wellknown technologies (such a medicine, medical devices and information systems). Many countries currently function with separate assessment bodies dealing with a specific type of technology. A few countries, such as Australia and France, have already addressed the challenge of stratified medicines by imposing a joint assessment of the diagnostic test, which allows the stratification of the target population and of the medicine; but this might not be sufficient to address challenges raised by brand new technologies, such as drugs containing nanotechnology to target tumours or clots.

153. Finally, countries continue to struggle to find the best way to **take people's preferences into account in priority setting**. While the involvement of stakeholders, including representatives of citizens, has become more common and methods such as MCDA are explored, there is no consensus and no real scientific evidence on how best to appreciate and consider people's preferences. This would be needed, however, to implement a decision process that sounds fair to citizens and patients and make decisions acceptable for the whole population.

154. **Beyond coverage decisions**, a big challenge for health systems is to ensure that new technologies are accessible and appropriately used. Efforts to rationalise the use of resources through adjustments of the range of benefits covered only make sense if recommendations are implemented in practice. Some countries, such as Israel, monitor effective access to newly covered technologies. Others have implemented utilisation reviews to improve patient safety, and appropriate use of medicines.

ANNEX A

Table A.1. Bodies in charge of assessment and/or appraisal and decision-making of procedures (PR), pharmaceuticals (PH) and medical devices (MD) in OECD countries

	Assessment/appraisal	Decision
Australia	PR -Medical Services Advisory Committee (MSAC) —also assesses in vitro diagnostic devices PH - Pharmaceutical Benefits Advisory Committee (PBAC) for pharmaceuticals used in outpatient care and private hospitals MD - Prostheses List Advisory Committee (PLAC) for a permanently implantable therapeutic device.	ALL : Ministry of Health, seeking agreement of the Cabinet for pharmaceuticals when budget impact is higher than AUD 20 million in any of the four years of the forward estimates.
Belgium	PR – Conseil technique médical PH - Medicine Reimbursement Commission MD - Commission for reimbursement of implantable and invasive medical devices	ALL: Ministry of Social Affairs
Canada	PR- No systematic assessment PH - Canadian Drug Expert Committee (CDEC), part of the Canadian Agency for Drugs and Technologies in Health (CADTH), performs assessment to inform all public plans but Québec's; the Expert Review Committee (pERC) performs assessment for oncology drugs for all public plans but Québec's. The Institut national d'excellence en santé et en services sociaux (INESSS) is responsible for review of new drug listings for public and private plans in Québec. MD – No common approach, depends on P/T	PR – P/T governments PH – P/T or central governments for public plans MD – Decisions largely decentralised, made by hospitals
Chile	ALL - Ministry of Health and the National Health Fund, National Institute of Public Health.	PR - Ministry of Health and the National Health Fund PH – National Institute of Public Health, Ministry of Health and the National Health Fund MD - Ministry of Health and the National Health Fund
Czech Republic	PR - MoH´s Health Procedure Catalogue Working Group PH - State Institute for Drug Control MD – no process defined	PR - Minister of Health PH - State Institute for Drug Control MD - General Health Insurance Fund

Denmark	PR – No systematic assessment PH - Danish Health and Medicines Authority's medical scientific advisory body (for new active substances) MD - Information not available	PR – No central decision in most cases. Danish Health and Medicines Authority, when procedures rely on a new medicine or medical device and for high specialised procedures. In other cases, no "central decision". PH - Danish Health and Medicines Authority MD – Information not available
Finland	PR – Assessment by local autonomous authorities PH - Pharmaceutical Pricing Board MD – Assessment by local autonomous authorities	PR - Local, autonomous authorities PH - Pharmaceutical Pricing Board MD - Local, autonomous authorities
France	 PR - Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDIMTS), part of the National HTA agency (HAS) PH - Commission de la Transparence, part of the National HTA agency (HAS) MD - Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDIMTS), part of the National HTA agency (HAS) 	PR - UNCAM (Union of health insurance funds) PH - Ministry of health MD - Ministry of Health
Greece	PR - Central Board of Health (KE.S.Y.) PH - National Organization for Medicines (EOF) MD - National Center for Quality Assessment and Technology in Health (EKAPTY)	ALL: Ministry of Health and EOPYY (National Organization for the Provision of Health Care Services)
Hungary	ALL - National Health Insurance Fund in Hungary	ALL - Minister responsible for Health
Iceland	PR – No assessment PH - The Price and Reimbursement Committee MD – No assessment	PR – Not applicable PH - The price and reimbursement committee MD - Not applicable
Israel	ALL - Medical Technology and Infrastructure Administration, part of the Ministry of Health (for assessment) and Public Committee (for appraisal)	ALL – Minister of health; Minister of Finance, National Health Insurance Law Council
Japan	PR - Expert Organization for Medical Fee-related Investigations PH - Drug Prices Organization MD - Expert Organization for Insurance Care Materials	ALL - Central Social Insurance Medical Council
Korea	ALL - Insurance Review and Assessment Service	ALL - Ministry of Health and Welfare
Luxembourg	PR - The Commission of Nomenclature PH - The National Health Fund MD - The Commission of Nomenclature/ The National Health Fund	PR - Minister of Social Security PH - President of the National Health Fund MD - Minister of Social Security or the President of the National Health Fund

Netherlands	ALL - National Health Care Institute	ALL - Minister of Public Health, Welfare and Sports (VWS), with agreement of the Parliament in some cases.
Norway	 PR - Norwegian Knowledge centre for health services (at national level) and the specialist health care (at local level). PH - The Norwegian Medicines Agency (NoMA), advised where needed by an external reimbursement committee (National Advisory Committee for Drug Reimbursement) MD - Norwegian Knowledge centre for health services (at national level) and the specialist health care (at local level). 	PR - The Regional Health Enterprises/Health Enterprises PH - The Regional Health Enterprises for medicines used in specialised health care; NoMA, Ministry of Health, the Parliament for drugs listed for general reimbursement. MD - The Regional Health Enterprises / Health Enterprises
Poland	ALL - Agency for Health Technology Assessment and Pricing	ALL - Minister of Health
Portugal	PR – No systematic assessment PH – INFARMED MD – No systematic assessment	PR - Not applicable PH - INFARMED or Ministry of Health MD - Not applicable
Slovak Republic	 PR – Information not available PH - Categorisation committee (1st line assessment body), Categorisation Council (2nd line assessment body) MD - Categorisation committee for medical device (1st line assessment body), Categorisation body for medical devices (2nd line assessment body) 	PR – Information not available PH - Ministry and Minister of Health MD - Ministry and Minister of Health
Slovenia	PR - Health Council (part of Ministry of Health) PH - Health Insurance Institute of Slovenia (HIIS) Commission for drugs MD – No systematic assessment	PR - Partners who accept General Agreement PH - HIIS Assembly MD - HIIS Assembly
Spain	ALL - Spanish Network of Agencies for Health Technology Assessment and Benefits of National Health System	ALL - Ministry of Health, Social Services and Equality, upon recommendation of the Commission of benefits, assurance and financing in which all Autonomous Communities are represented
Sweden	PR – Information not available PH – The Dental and Pharmaceutical Board (TLV) MD -Information not available	PR – Information not available PH – The Dental and Pharmaceutical Board (TLV) MD - Information not available
Switzerland	ALL – the assessment process is systematic, but not all benefits are assessed. PR -Eidgenössische Kommission für Allgemeine Leistungen und Grundsatzfragen (including medical devices which are part of a medical procedure) PH - Eidg. Arzneimittelkommission	 PR - New procedures are reimbursed by default; exclusion from or limiting of reimbursement is decided by the Federal Department of Home Affairs PH - Federal office of public health MD - Federal Department of Home Affairs; therapeutic devices used as part of a procedure (implants, etc.) are reimbursed by default if not excluded from reimbursement (see under procedure). Listing of laboratory tests: Federal

	MD - Eidg. Kommission für Analysen, Mittel und Gegenstände (Ausschuss für Mittel und Gegenstände) for therapeutic devices applied by patients and non-professional carers only! Other: Eidg. Kommission für Analysen, Mittel und Gegenstände (Ausschuss für Analysen) for lab analyses	Department of Home Affairs
Turkey	PR - The Commission of Health Service Pricing PH - Medical and Economic Assessment Commission MD - Medical Devices Reimbursement Commission	PR - Social Security Institution - The commission of Health Services Pricing PH - Social Security Institution and Reimbursement Committee MD - Social Security Institution and Reimbursement Committee
United Kingdom	ALL – no systematic assessment. The National Institute for Care Excellence commissions an independent academic centre to technically review the evidence submissions and prepare an Evidence Review Group (ERG) report. Others: The UK National Screening Committee (UKNSC) advices government on screening programs	 PR – No "listing" for procedures. NICE (National Institute for Health & Care Excellence) when an assessment is performed MHRA (Medicines and Healthcare Products Regulatory Agency) and the NSC (National Screening Committee) makes decision for screening PH - NICE (National Institute for Health & Care Excellence) when an assessment is performed MD - MHRA (Medicines and Healthcare Products Regulatory Agency) provides marketing authorisation, no further "listing"
United States	ALL - For Medicare only: the Centers for Medicare and Medicaid Services (CMS) carries out the assessment or commissions HTA and/or consultations with Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).	ALL: CMS for Medicare. Private health insurers make decisions on coverage, with some obligations for plans participating to health insurance exchanges.

Source: 2014 OECD Questionnaire for the Health Benefit Basket Project.

Countries	Health care technologies
Belgium	Medication used in the treatment of Alzheimer's Disease (lack of proven efficiency) new treatments of Hepatitis C (issues with pricing), the new geriatric tests (NGS), the NIPT test, non- medical AIDS screening
Canada	When services that would otherwise be insured are provided in private clinics, some plans exclude them from reimbursement under the PT health plan. Such services include abortion services and diagnostic imaging.
Korea	Bariatric surgery, assisted reproductive technology, smoking cessation products, cavity in children, palliative care services, breast reconstruction after mastectomy
Luxembourg	Obesity treatment in national spa centre: the programme itself, its link to bariatric surgery, minimum BMI
Norway	Different types of cancer drugs, all available on https://nyemetoder.no/metoder
Spain	 Increase age for coverage of hearing aids Include the opportunistic cervical cancer screening in the population screening programme Extend the current population screening programme of endocrine metabolic diseases to new disorders Extend the use of cushions in preventing pressure ulcers to include other groups of population
Switzerland	Non-invasive prenatal tests (potential to reduce drastically the amount of invasive prenatal tests, open question: reimbursement to women with elevated T21 risk determined with first-trimester-test, or to all women? Psychotherapy by self-employed psychologists (so far reimbursed only, if psychologists are employed by psychiatrists) Mammography / MRI in women with moderate or high risk for breast cancer (according to NICE guideline and in competence centers instead of uncoordinated care)
United Kingdom	Cervical screening, in the light of HPV immunisation programme, Screening for bladder cancer should not be offered. This has been reviewed as part of the Cancer Reform Strategy for England. Screening by urine dip stick testing for protein and blood is not recommended and should no longer take place. E- cigarettes, Long-term care funding

Table A.2. Technologies currently being discussed for exclusion or inclusion to the range of benefits covered

Source: 2014 OECD Questionnaire for the Health Benefit Basket Project.

Table A.3. The common forms of revision and the frequency applied recently across OECD countries

	Policies targeting the benefit basket
Australia	 Withdrawals happen rarely, for instance when a pharmaceutical product after a review is no longer found cost-effective (e.g. Anakinra for the treatment of severe active rheumatoid arthritis), or if the sponsor itself decides to withdraw the product from the market. For procedures and pharmaceuticals, coverage conditions change frequently. E.g. in 2014, four mastectomy items were merged into three, removing the gender specific terminology. Typically, for pharmaceuticals, an extension of indication following a new application from a sponsor company will lead to changes in conditions, e.g. Bevacizumab for the treatment of colorectal cancer was recently extended to also cover treatment for ovarian cancer. Changes in reimbursement level occur occasionally. A review of the price of gliptins for the treatment of diabetes following the listing of a new product in December 2013 resulted in a price cut to all other gliptins. Risk-sharing arrangements which can take the forms of caps and/or rebates are in place for a number of high cost medicines following recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC). All of these agreements are commercial in confidence. Industry may request a benefit review. But they will need to support their request with sufficient evidence to support a benefit change
Belgium	Withdrawal of benefits happens rarely, e.g. removing packages where the dosage is not scientifically relevant/proven. Changes in reimbursement conditions occur frequently, for instance in order to harmonise reimbursement conditions of specialities within the same category Occasionally, the reimbursement level is changed in order to align reimbursement amounts in a cluster of medicines with similar indications.
Canada	Delisting of insured services is rare but increasing in recent years, especially for diagnostics. Some provinces have delisted regular eye exams for the general population, physiotherapy outside hospitals and PSA tests for men under 50. Coverage for eye exams and dental care is sometimes directed at specific populations and the coverage levels can change over time. Changes in reimbursement conditions are rarely implemented, since the first-dollar coverage for medically necessary hospital and physician services is covered under statute. It would occur chiefly when coverage for additional benefits to targeted populations (the poor, seniors, children) changes. While the percentage coverage of core services does not change (100%), the amounts physicians are reimbursed in the fee schedule have recently been the focus in some P/Ts with reimbursement levels decreasing in areas where there has been technological change. For example, the cataract surgery fees in Ontario have recently been reduced.
Chile	Withdrawals and/or replacement of services happen rarely, but were seen for varicose veins where external saphenectomy was replaced bendovenous laser ablation. Procedures have been modified as well, for example in the case of cataract surgeries where most of the surgeries are considered as ambulatory. The reimbursement level and cost-sharing in the public sector is defined by law and the government cannot change it.

Czech Republic	Delisting of drugs with no clinical effectiveness evidence (e.g. Orlistat for obesity, cinnarizin). The reimbursement level of drugs often decreases according to the benchmark prices. OTC medicines were delisted in 2012.
Denmark	The expensive opioids like Palexia are not eligible for reimbursement. The price of this opioid is very high comparing to other opioids.
Estonia	Reduction in coverage of dental care. Before 1 January 2009, people over 19 could apply for the dental care benefit of EEK 300 (EUR 19.18). Since then, this benefit is limited to persons over 63 years of age, people for incapacity benefits or old-age pensions.
Finland	 Delisting of services happens rarely, for instance following the decrease in price of alternative treatments. Occasionally coverage conditions change when the therapeutic value of a drug has changed. The reimbursement level is rarely subject to change, but it would occur in the event when criteria for higher reimbursement level are no longer met, for example when the indication of a drug has changed.
France	Delisting of service mainly concerns procedures that are no longer practical. There is a systematic reassessment of pharmaceuticals every five years, and recently the passing of a new law in 2015 requires that all newly registered devices should be reviewed every five years.
Greece	Unification of benefit packages among the various SHI funds (2011), and age restrictions to diagnostic tests have been applied.
Iceland	Withdrawals of pharmaceuticals from the benefit basket occur very rarely. Changes in coverage conditions take place in cases where maximum reimbursement levels are introduced for groups of interchangeable pharmaceuticals, for example the in case of PPI medicines.
Ireland	From 2010, a cut of EUR 30 million to dental care for medical card holders.
Israel	Delisting of services and/or benefits never happen in the Israeli health care system. Changes in the coverage conditions are applied frequently, but only to broaden the set of reimbursed indications. Changes in reimbursement level can only be implemented by public committees, and have been applied to hearing aids, contraception and physical therapy for cystic fibrosis patients.
Japan	 Pharmaceutical products for which companies request to exclude based on reasons such as availability and reduced demand will be subject for delisting from the benefit basket on a regular basis. Similarly, procedures are revised every two years and may lead to delisting, whereas medical devices will only be withdrawn in the event of discontinuation of manufacturing and sales. Changes in the coverage conditions happen regularly for pharmaceutical products and procedures, either in line with the content of the drug authorisation process or based on the initiative of the companies to expand coverage. Cost-sharing is not revised for a specific treatment but it can be changed as part of the entire health insurance system which takes place on rare occasions.
Luxembourg	Pharmaceutical products, for example topical rubeficiants and nasal decongestants, have been delisted from the benefit basket. Rarely, coverage conditions for pharmaceutical products change, but it has happened in the case of anticancer drugs.

Netherlands	The benefit basket is reviewed once per year, and withdrawals and changes in coverage conditions occur as part of this review process. From 2010, the coverage conditions changed for reimbursement of IVF and other fertility treatments to only cover three attempts for those under 43 years of age; the number of physiotherapy sessions to be paid for by the patient increased and specific conditions apply for those suffering from certain chronic diseases and/or incontinence; coverage of non-acute care outside the EU was removed and requires bilateral agreements with certain countries; mental health services restricted and psychological care reimbursement reduced from eight to five sessions. It happens rarely that the target population is being restricted after the intervention has already been included in the benefit basket, but it does happen. The main changes in reimbursements level concern the general deductible. For some pharmaceuticals also co-payments are asked but these are less prone to change.
Poland	Delisting of pharmaceuticals, procedures and medical devices included in the benefit basket rarely occurs, but it happened for drugs funded under "non-standard chemotherapy" and drugs used in off-label indications (a positive list for funding in off-label uses exist in the system). General forms of revision leading to changes of the coverage conditions of services included in the benefit basket or changes in the corresponding reimbursement levels do not exist.
Portugal	Pharmaceutical products are sometimes withdrawn from the benefit basket. From 2011, the following health services under ADSE (the health system for public sector workers) have been delisted: services regarding working accidents and professional diseases, clinical trials, unconventional therapeutics and aesthetic surgery. Also, delisting of some drugs can take place on a rare basis. Changes in coverage conditions for pharmaceuticals rarely happen due to approval of few indications.
Slovak Republic	Pharmaceutical products and medical devices are rarely withdrawn from the benefit basket, but it does occur. Changes in coverage conditions for pharmaceutical products and medical devices are applied frequently following a request from companies. Similarly, adjustments of the reimbursement levels are implemented frequently.
Slovenia	According to the Health care and health insurance act, the HIIS Assembly is authorised to change the level of CHI coverage for services, drugs and devices (co- payments) and it occasionally did so. Changes in coverage conditions and reimbursement levels were more often directed at pharmaceutical products and medical devices.
Spain	Changes in coverage conditions occur sometimes, in case of obsolete technology, for example by the exclusion of gamete intra-fallopian transfer. Sometimes the indications for better use are dimensioned leading to an automatic change in reimbursement level; Ventricular assistant device in the following indications: - As a bridge to transplantation (temporary or short-term) when the patient is hemodynamically compromised or refractory to drug therapy, - As a bridge to recovery in patients with unresponsive acute heart failure to conventional therapy and having chance of myocardial recovery, as cardiogenic shock and severe acute myocarditis - As destination therapy (permanent or long-term) for patients who are not candidates for transplantation, with an ejection fraction of the left ventricle ≤25% and NYHA class with IIIB / IV and peak VO2 <14 mL / kg / min, despite being under optimal inotropic treatment.

SwedenDelisting, changes in coverage conditions and reimbursement level of pharmaceutical products happens rarely and is mainly related to pate			
Switzerland	Since the beginning of 2011, eyeglasses are no longer covered by mandatory health insurance for adults without specific health needs. Changes in coverage have been applied for example for indications for PET/CT- scans; vaccination schedules; eye glasses, reimbursement limited to children and persons with severe visual problems In the case of pharmaceuticals, the reimbursement level and prices are reviewed every three years, and some of these are adapted accordingly. The reimbursement level for procedures is never changed, as it negotiated between payer and provider and cost-sharing is uniform for all providers. For devices and lab analyses, the reimbursement level is negotiated and potentially changed on an occasional basis.		
Turkey	Pharmaceutical products are frequently revised and conditions changed according to changes in the indication of drugs.		

to changes in the indication of drugs. Source: 2014 OECD Questionnaire for the Health Benefit Basket Project, 2012 OECD Health Systems Characteristics Survey, Health In Transition (World Health Organization).

Table A.4. Coverage of interventions whose effectiveness is questioned: Homeopathy

Countries	Is homeopathy covered by basic health insurance?	Is supplementary health insurance available?	Was homeopathy subject to HTA?
Australia	No	Not available	Part of ongoing review of the Australian Government Rebate on Private Health Insurance for Natural Therapies, see: http://www.health.gov.au/internet/main/publishing.nsf/Content/phi- natural-therapies
Belgium	No	Yes	Not available
Canada	No	Varies by plan, PHIs available	Not available
Chile	No	No	No
Czech Republic	No	Not available	No.
Finland	No	Not available	Not available
Greece	No	No	Not available
Hungary	No	Not available	Not available
Iceland	No	No	No
Israel	No	Limited coverage by supplementary health insurance schemes.	No
Japan	No	Not available	No
Korea	No	Not available	Not available
Luxembourg	Yes, but only if mentioned in the positive list. In order to qualify for the positive list, the product must be made out of a single stock of vegetable, mineral or chemical origin and marketed in form of globules, granules, tablets or drops.	Not available	Homeopathic drugs have not been assessed. Their coverage has been granted as part of a governmental plan.

Netherlands	No	Some health insurers do offer homeopathy remuneration in supplementary private health insurance schemes. The amount of services/products remunerated and the changes in premium differ between insurers.	Νο
Norway	No	Not available	Not available
Poland	No	Not available	No
Portugal	No	Not covered. Recently regulated. The major activity is developed by professionals in private practices.	Νο
Slovenia	No	No	No
Spain	No	No	Not available
Switzerland	Yes, but only by physicians with conventional and homeopathy training, under CED	By non-medical therapists: sometimes covered by private insurance (depending from contract)	Yes (1999-2005). Efficacy not proved; primary care physicians using homeopathy deliver economic care; patients are satisfied.
Turkey	No	Not available	Not available
United States	Medicare: No	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire.

Table A.5. Coverage of interventions whose effectiveness is questioned: Acupuncture

Countries	Is acupuncture covered by basic health insurance?	Is supplementary health insurance available?	Was the acupuncture subject to HTA?
Australia	Covered (with restrictions). Acupuncture services can be claimed from the MBS when provided by GPs – restrictions apply.	Acupuncture services may also be provided by private health insurance companies, depending on the policies they choose to provide their members.	No.
Austria	Covered for pain alleviation if provided by qualified physicians.	Not available	Not available
Belgium	No	Sometimes, by some sickness funds as a complementary insurance. PHI covers if acupuncture is provided by qualified physicians, dentists and midwives that are registered as providers of acupuncture services, up to a certain number of sessions per year.	Not available
Canada	No, except in British Colombia	In BC available to those receiving premium assistance, PHIs exist and coverage varies by province	Not available
Chile	No	No	No.
Czech Republic	No	Not available	No.
Denmark	Covered if provided by an authorised doctor or under the supervision of and after delegation by a doctor.	Not available	Not available
Finland	No	Not available	Not available
France	Yes	Not available	Not available
Germany	Covered for chronic pain of the knee joint (gonarthrosis) and the lumbar spine. In order to bill the sickness fund for their services, providers need to have qualification in acupuncture and a proof of knowledge in the areas of psychosomatic basic care and pain treatment.	Not available	Not available
Greece	No	No	Not available
Hungary	No	Not available	Not available

Iceland	Yes, according to contract between the Health Insurance and physical therapists	Not available	No
Israel	No	Limited coverage by supplementary health insurance schemes.	Not available
Italy	No	Not available	Not available
Japan	Covered as part of treatment for certain chronic diseases. Treatment cost is subsidised if provided as part of treatment for certain chronic diseases and doctor's approval is available.	Not available	No
Korea	Yes, limited to twice per day in inpatient care; once per day in outpatient care	Not available	Not available
Luxembourg	No	Yes, some supplementary health insurances cover this activity.	Not available
Netherlands	Νο	Some health insurers do offer osteopathy remuneration in supplementary private health insurance schemes. The amount of services remunerated and the changes in premium differs between insurers.	No
Norway	No, except for women giving birth in midwifery units.	Not available	Not available
Poland	Covered for chronic pain treatment. It is accessible only with a referral from a physician contracted by the National Health Fund (NFZ). Medical indication determined by law, only in the treatment of pain	Not available	No
Portugal	No	Not covered. Recently regulated. The major activity is developed by professionals in private practices.	No
Slovak Republic	Partly	Not available	Not available
Slovenia	Covered for pain syndromes	Νο	Approved by the Health Council (MoH)
Spain	No	No	
Sweden	Yes	Not available	Not available
Switzerland	Yes, only when provided by physicians with conventional and acupuncture training	By non-medical therapists: sometimes covered by private insurance (depending from contract)	No
Turkey	No	Not available	Not available

United Kingdom	Yes, clinical decision by a physicians	Not available	Not available
United States	Medicare: No	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.6. Coverage of interventions whose effectiveness is questioned: Herbal medicine

Countries	Is herbal medicine covered by basic health insurance?	Is supplementary health insurance available?	Was herbal medicine subject to HTA?
Australia	No	Not available	Part of ongoing review of the Australian Government Rebate on Private Health Insurance for Natural Therapies, see: http://www.health.gov.au/internet/main/publishing.ns f/Content/phi-natural-therapies
Belgium	No	Sometimes, by some sickness funds as a complementary insurance	Not available
Canada	No	Varies by plan, PHIs exist.	Not available
Chile	No	No	No
Czech Republic	No	Not available	No
Denmark	No	Not available	Not available
Finland	No	Not available	Not available
Greece	No	No	Not available
Hungary	No	Not available	Not available
Iceland	No	No	No
Israel	No	Limited coverage by supplementary health insurance schemes.	No
Japan	No	Not available	No
Korea	No	Not available	Not available
Luxembourg	Yes, applications for coverage of herbal drugs are treated equally to applications for other drugs. A medical prescription is necessary for the reimbursement	Not available	Yes

Netherlands	No	Some health insurers do offer remuneration of herbal medicine in supplementary private health insurance schemes. The amount of products remunerated and the changes in premium differ between insurers.	Νο
Norway	No	Not available	Not available
Poland	No	Not available	Not available
Portugal	No	Not covered. Recently regulated. The major activity is developed by professionals in private practices.	Νο
Slovenia	No	No	No
Spain	No	No	Not available
Switzerland	Drugs, traditional Chinese medicine and additional consultation time of physicians: only by physicians with conventional and phytotherapy training, under CED. Many herbal medicine drugs are included in the "Spezialiätenliste" and therefore reimbursed.	Drugs not included in the formulary, or prescribed by non-medical therapists: sometimes covered by private insurance (depending from contract)	Primary care physicians using homeopathy, phytotherapy or traditional Chinese medicine deliver economic care.
Turkey	No	Not available	Not available
United Kingdom	No	No	Not available
United States	Medicare: No	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.7. Coverage of interventions whose effectiveness is questioned: Osteopathy

Countries	Coverage of osteopathy by basic health insurance	Is supplementary health insurance available?	Was osteopathy subject to HTA?
Australia	Yes covered by the Medical Benefit Schedule.	Not available	Not available
Belgium	No	Sometimes, by some sickness funds as a complementary insurance. PHIs cover if osteopathy is provided by qualified physicians, dentists and midwives who are registered for acupuncture services, up to a certain sessions per year.	Not available
Canada	No, the conditions vary by province	Varies by plan, PHIs exist.	Not available
Chile	Yes, it is covered. For all the people who need to be treated in this pathology, and diagnosed by a physician and decision authorised by third-party payer	Not available	No
Czech Republic	Yes, covered when recommended and referred by physician.	Not available	No
Finland	No	Not available	Not available
France	Yes, doctor's consultation related to osteopathy is covered but actual osteopathy is not covered.	Yes, some PHIs are available	Not available
Hungary	No	Not available	Not available
Iceland	No	No	No
Israel	No	Limited coverage by supplementary health insurance schemes.	No

Japan	No	Not available	No
Korea	No	Not available	Not available
Luxembourg	Νο	Yes, some supplementary health insurances cover this activity.	Not available
Netherlands	Νο	Some health insurers do offer osteopathy remuneration in supplementary private health insurance schemes. The amount of services remunerated and the changes in premium differs between insurers.	Νο
Norway	No	Not available	Not available
Poland	No	Not available	No
Portugal	Νο	Not covered. Recently regulated. The major activity is developed by professionals in private practices.	No
Slovenia	No	No	No
Spain	No	No	Not available
Switzerland	Νο	Sometimes covered by private insurance (depending from contract)	No
Turkey	No	Not available	Not available
United Kingdom	Yes, the clinical decision is made by the physician	PHIs available	Not available
United States	Medicare: Yes, when the care is provided by a doctor of osteopathy	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.8. Coverage of interventions whose effectiveness is questioned: Spa treatment

Countries	Is spa treatment covered by basic health insurance?	Is supplementary health insurance available?	Was spa treatment subject to HTA ?
Australia	No	Not available	Not available
Belgium	No	Yes	Not available
Canada	No	Varies by plan, PHIs are available.	Not available
Chile	No	No	No
Czech Republic	Yes, Full or partial coverage based on recommendation by physician and confirmation by a revision authority.	Not available	No
Finland	No	Not available	Not available
France	Yes	Not available	Not available
Greece	Coverage for specific conditions. There are also specific periods for beneficiaries once a year from 1/6 to 31/10	Not available	Not available
Hungary	Yes, when prescribed by physician, 6-80 times per year depending on the type of care	Not available	Not available
Iceland	No	No	No
Israel	No	No	Not available
Japan	No	Not available	No
Когеа	No	Not available	Not available

Luxembourg	Prior authorisation Social Security Medical Inspectorate (CMSS) is mandatory. The authorisation must take into account a recommendation from the treating specialist and a prescription from a medical specialist working at the spa centre (there is only one spa centre "Centre thermal et de santé de Mondorf-les-Bains which has an agreement with the CNS). The benefits provided are reimbursed at a rate of 80%. Currently, lodging costs are reimbursed with 50,39€ per day. Spa treatments that are interrupted without any valuable reason are not reimbursed. Except for treatments of the back, shoulders and neck, a spa treatment can only be authorised once a year.	Not available	Not available
Netherlands	Netherlands No Some health insurers do offer spa treatment remuneration in supplementary private health insurance schemes. The amount of services remunerated and the changes in premium differs between insurers.		Νο
Norway	No Not available		Not available
Poland	Yes	Not available	Not available
Slovenia	Yes for rehabilitation after specific diseases	No	Defined in Regulation of CHI
Spain No No		No	Not available
SwitzerlandCoverage for specific conditions. There are also specific periods for beneficiaries once a year from 1/6 to 31/10		Yes, depending from contract	No
Turkey	No Not available		Not available
United Kingdom	No	No	No

United States	Medicare: No	Not available	Not available

Note: The table only includes information from responding countries.

Source: 2014 OECD Health Benefit Basket Questionnaire

Cour	ntries	Is bariatric surgery covered by basic health insurance?	Is suppleme ntary health insurance available?	Was the activity subject to HTA?
Aust	ralia	Yes (MBS). Medicare benefits can be claimed for several types of bariatric surgery, including gastric banding, gastric bypass and sleeve gastrectomy. Medicare benefits are payable for bariatric surgery where it is: - clinically relevant, in other words, generally accepted in the medical profession as being medically necessary for the appropriate treatment of the patient, and - performed in accordance with State and Territory laws. Items 31569 to 31581 and item 20791 provide for surgical treatment of clinically severe obesity and the accompanying anaesthesia service (or similar). The term clinically severe obesity generally refers to a patient with a Body Mass Index (BMI) of 40kg/m2 or more, or a patient with a BMI of 35kg/m2 or more with other major medical co-morbidities (such as diabetes, cardiovascular disease, cancer). The BMI values in different population groups may vary due, in part, to different body proportions which affect the percentage of body fat and body fat distribution. Consequently, different ethnic groups may experience major health risks at a BMI that is below the 35-40 kg/m2 provided for in the definition. The decision to undertake obesity surgery remains a matter for the clinical judgment of the surgeon.	Not available	In 2012, the Medical Services Advisory Committee completed a comprehensive review of the safety, effectiveness and cost- effectiveness of bariatric surgery and concluded that obesity is a significant population health issue that has implications for both short and with longer term medical issues. MSAC found that bariatric surgery is an effective and cost effective treatment for obesity: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Ob esity_+Review

Table A.9. Coverage of interventions with risk of inappropriate use: Bariatric Surgery

Belgium	Yes. Minimum age 18 years, BMI >40, or BMI>35 combined with diabetes, obstructive apnoea syndrome (during sleep, breathing stopped too long leading to reduced sleep quality and increased fatigue during the day), hypertension (>140/90 mmHg) despite intake of three different types of hypertension, or BMI>35 prior to a new surgical intervention after an earlier failed intervention. Having followed for at least 1 year a diet without sustainable results and where surgery is the last option. Readiness to adapt eating and life-style after surgery. Final approval by multidisciplinary team (surgeon, psychologist, endocrinologist, nutritionist.	Not available	Not available
Canada	Yes in some provinces	Varies by plan, PHIs are available	
Chile	Yes; target population: patients with Body Mass Index (BMI) greater than 40 kg / m 2 or> 35 kg / m 2 with significant co-morbidities. Prescribed by physician. The third party payer does not authorize each case, but the provider negotiates with annual quotas.	Not available	Yes. It resulted as cost-effective and has been covered by some public health care providers and private insurers.
Czech Republic	Νο	Not available	Νο
Finland	Varies by region. Decisions made by local, autonomous authorities	Not available	Not available
France	Covered for people aged 18-60 with BMI > 40 kg/m ² , or > 35 kg/m ² with associated complication (such as type 2 diabetes) who had already tried losing weight with specialised medical care for the past few months but without success. Decision to perform surgery is made by a multidisciplinary team. Prior authorisation is not required for the coverage.	Not available	Not available
Hungary	Yes. Starting at BMI>35 and BMI decrease 10 min and lost weight stable for min 6 months	Not available	Not available
Iceland	No	No	No

Israel	Yes. Covered for treatment of severe obesity according to standard medical guidelines: For BMI>40 and after failure to lose weight via conventional approaches, and for BMI>35 for patients suffering also from related disease such as HTN, ischemic heart disease, diabetes, and sleep apnoea.	Not available	Yes
Japan	Yes, laparoscopic sleeve gastrectomy for those who did not have a sufficient outcome after more than 6 months of medical treatment and who have BMI of over 35. Treatment should be provided by doctors with more than 5 years of experiences in treating hypertension, dyslipidaemia or diabetes.	Not available	Νο
Korea	No (under discussion)	Not available	Cost-effective
Luxembourg	Yes. Prior authorisation Social Security Medical Inspectorate (CMSS) is mandatory. Minimum age requirement: 18. BMI > 40, or =>35 plus at least one comorbidity that might improve following surgery (Hypertension resistant to treatment and defined by an increase in arterial blood pressure above 140/90 mmHg; severe metabolic problems, obstructive sleep apnoea proven by polysomnography; incapacitating bone and joint diseases; non- alcoholic steatotic hepatitis). The insurance holder must have undergone a medical, nutritional, dietary and psychotherapeutic treatment of at least 6 month that did not result in a sufficient weight loss or weight loss at all. The follow-up of the treatment has to have taken place in a hospital with a unit performing bariatric surgery. The decision to perform a bariatric surgery has been taken by a multidisciplinary team composed of at least a surgeon, an internal medicine specialist, a psychiatry specialist, and one dietician. The report of these meetings stating the operative indication has to be signed by the four specialized participants listed above and must be sent together with the data on dietary treatment to the CMSS. The insured person may not have benefited from bariatric surgery before, if it does not concern a re-intervention after a complication of a prior bariatric procedure. The insured person has to have signed an informed consent	Not available	Not available

Netherlands	Yes. Bariatric surgery is only remunerated from basic health coverage if: - Patients have followed an intense (dietary and contra-sedentary) lifestyle intervention for at least a year, with insufficient success - Patients have a BMI≥40 (or ≥35 if combined with other diseases)	Not available	Yes. ZIN found that sleeve gastrectomy is a scientifically valid and cost-effective treatment. It also concluded that there is not sufficient scientific evidence that bariatric surgery is helpful for people with diabetes mellitus type 2 and a BMI <35.
Norway	Yes, covered for persons with morbid obesity (body mass index (BMI) \ge 35 kg/m2 with at least one obesity related comorbidity or BMI \ge 40 kg/m2) when other treatments have been ineffective.	Not available	Not available
Poland	Yes, bariatric surgery is performed on the basis of clinical indications.	Not available	It was not the subject of health technology assessment.
Portugal	Covered. Coverage conditions are defined by the General Health Directorate (DGS). A patient is enrolled in the programme if certain characteristics are present (such as minimum BMI, age, number of years with consecutive obesity, associated diagnosis, etc). A number of accessibility and quality indicators is contracted with each recognized treatment centre.	Not available	Not available
Slovenia	Pathological obesity - on decision of specialist	No	Approved by the Health Council (Ministry of Health)
Spain	Prescription by physician when being diagnosed with morbid obesity	Not available	Not available
Switzerland	Yes. Surgeries are performed in competence centres, BMI 35 or higher, if conservative treatment > 2 years has failed	Not available	Under CED for > 6 years; results of CED led to the limitation to competence centres with focus on prudent patient selection, quality of surgical procedure, and long term follow up
Turkey	SSI pays the condition of the patient's surgical intervention be decided by medical board which composed of six experts (surgeons, gastroenterologists, endocrinologists.) in different fields within hospitals.	Not available	Not available
United Kingdom	Covered with conditions following clinical decision by physician	Not available	Yes, by NICE
United States	MedicAid covers bariatric surgeries under the following conditions; BMI>35, at least one obesity-related comorbidity, has documentation proving that previous attempts at medical treatment of obesity has been unsuccessful	Not available	Not available

Note: The table only includes information from responding countries.

Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.10. Coverage of services that are provided by non-physicians: Psychological therapy

Countries	Is psychological therapy covered by basic health insurance
Australia	Covered and cognitive behavioural therapy is available in primary care.
Austria	Covered and cognitive behavioural therapy is available in primary care.
Belgium	Covered and cognitive behavioural therapy is available in primary care.
Canada	Typically covered only through employee insurance schemes and they sometimes cover services provided by psychologists or social worker.
Chile	Covered fully in the public sector but partially in the private sector. In the private sector, coverage is up to a certain threshold, usually between two to twelve sessions, depending on health insurance plans.
Czech Republic	Covered.
Estonia	Not covered.
Finland	Covered.
France	Covered as long as provided by psychiatrist or in outpatient, multidisciplinary clinics (Centres Médico-Psychologiques)
Germany	Covered up to 100 hours of psychological psychotherapy. Children are entitled to 150 hours of psychological psychotherapy, and 180 hours for adolescents.
Hungary	Not covered.
Iceland	Covered and cognitive behavioural therapy is available in primary care.
Ireland Covered if provided through public health system.	
Israel	Services provided by the government's network of mental health centres are covered and generally covered up to 10 hours but this has not been strictly enforced. Services provided by private therapists are not covered. But services provided by health plans may be covered by PHI but mental health services provided by primary care physicians are covered.
Italy	Covered.
Japan	Covered.
Korea	Covered and cognitive behavioural therapy is available in primary care.
Luxembourg	Covered and cognitive behavioural therapy is available in primary care.
Mexico	Public services are covered but not private services.
Netherlands	Covered up to 5 sessions.
New Zealand	Not covered.
Norway	Covered and cognitive behavioural therapy is available in primary care.
Poland	Not covered by the publicly-managed system.
Portugal	Covered.
Slovak Republic	Covered.

Slovenia	Covered.
Spain	Not covered but the benefit basket for mental health care and rehabilitation has been broadened and community-based services have been included in recent years.
Sweden	Covered and cognitive behavioural therapy is available in primary care.
Switzerland	Covered only when services are provided by a physician (psychiatrist or physician with additional training in psychotherapy) or by a psychologist employed by a psychiatrist or psychiatric institution. Reimbursement is restricted to psychotherapies in case of mental disease (not for counselling / coaching etc.)
Turkey	Covered.
United Kingdom	Covered and cognitive behavioural therapy is available in primary care.
United States	The coverage depends on health status, and the terms of the insurance held by the individual or public program in which they are enrolled.

Note: The table only includes information from responding countries. Source: OECD (2014b) *Making Mental Health Count.*

Table A.11. Coverage of interventions which can potentially be financed by users: Over-the-counter medicines

Countries	Coverage of OTC medicines by basic health coverage	Coverage by supplementary private health insurance
Australia	Most OTC products are not subsidised by the government. Only a small number of over the counter medicines are listed on the PBS - and subsidised only when prescribed by a health professional.	Not available
Belgium	No	No
Canada	Covered for inpatient settings but not covered outside hospitals but coverage conditions vary across regions.	Varies by plan, PHIs are available.
Chile	No.	Yes, by private health insurance
Czech Republic	Generally not covered, except when included in a short list of medicines covered for patients with specific conditions	No
Denmark	OTC medicines are generally not covered. Reimbursement is only granted if the medicine is dispensed on prescription to persons covered by the reimbursement condition, meaning, for example, that they suffer from specific diseases.	Not available
Finland	OTC drugs are covered if reimbursements were applied and reimbursement status granted	Not available
France	OTC medicines are reimbursed when included in the positibe list and prescribed by a physician	Not available
Germany	No, except when short-listed by the GBA for patients with specific conditions.	Not available
Greece	Νο	Usually not included in the contracts
Hungary	No	Possible by private insurance, social services (közgyógy).
Iceland	No	No
Israel	Covered but specific conditions apply to each drug.	Not available
Japan	No	Not available
Korea	No	Not available
Luxembourg Applications for coverage of non-prescription drugs are treated equally to applications for prescription-only drugs. A medical prescription is necessary for the reimbursement of over-the-counter drugs .		Not available
Mexico	Not available	Not available

Netherlands	OTC drugs of the following categories can be reimbursed when prescribed by a doctor, and part of the basic package: - Laxatives - Calcium tablets - Pharmaceuticals for the treatment of allergies - Anti-diarrheal pharmaceuticals - Anti-emetics - Pharmaceuticals for dry eyes	Not available
Norway	No	Not available
Poland	No	No
Slovenia	Only when provided in pharmacies	No
Spain	No	No
Sweden	No	Not available
Switzerland	OTC drugs are covered only when included in the positive list, prescribed by a physician, provided that there is no direct-to- consumer advertising	Yes, partly
United Kingdom	No	No
United States	Medicare:No	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Countries	Are contact lenses and/or glasses covered by basic health insurance?		
Australia	Not covered. PHI is available for services not listed on the Medicare Benefits Schedule and covers ancillary services including prescription spectacles.		
Austria	Covered.		
Belgium	Covered only the people with vision above/below a dioptre threshold.		
Canada	Coverage depending on regions or health insurance funds but most provincial and territoria governments offer and fund a range of supplementary benefits for certain groups (e.g., low-income residents and seniors), such as vision care that are not covered under the Canada Health Act and supplementary health services are covered by an employment-based group insurance plan, or private insurance. Under most provincial and territorial laws, private insurers are restricted from offering coverage that duplicates that of the publicly funded plans, but they can compete in the supplementary coverage market.		
Chile	Covered but the coverage depends on the type of health insurance institution and sometimes insurance schemes.		
Czech Republic	Subsidy for those with high health expenditure for the cost related to eyeglasses and/or contact lenses.		
Denmark	Not covered.		
Finland	Not covered.		
France	Covered.		
Germany	Covered for those who are 18 years of age or younger, or for those with severe visual impairment. Subsidy for those with high health expenditure for the cost related to eyeglasses and/or contact lenses.		
Greece	Covered.		
Hungary	Covered 2 eyeglass lenses per eye per 24 months and 2 contact lenses per eye per 12 months. People receiving social benefits are also covered.		
Iceland	Not covered.		
Ireland	Covered standard frames are covered without any charge. PHIs are available.		
Israel	Not covered.		
Italy	Covered for certain population groups but coverage depending on regions. Many PHIs are available for eyeglasses.		
Japan	Not covered.		
Korea	Covered for people with specific medical needs.		
Luxembourg	Covered one pair of glasses is covered every three years.		
Mexico	Not covered.		
Netherlands	Not covered. PHIs are available for eyeglasses and contact lenses.		
New Zealand	Contact Lens Subsidy for people assessed by a specialist as having an eye condition and requiring contact lenses. Subsidies for children aged 15 and under with Community Services Card for low to middle income people or High Use Health Card for frequent health service users. PHIs are available.		
Norway	Covered for people with specific medical needs.		
Poland	Covered one pair of glasses is covered every two years. Contact lenses are also covered but only if connected to treatment of specific diseases.		
Portugal	Covered for low income elderly.		
Slovenia	Covered.		

Table A.12. Coverage of interventions which can potentially be financed by users: Vision products

Sweden	Covered.
Switzerland	One pair of glasses is covered every year for children with any vision problems and every five years for adults with severe vision problems. Those with specific medical needs (such as a chronic health condition) are also covered.
Turkey	Covered for the retired and their dependents.
United Kingdom	Covered for people with low income, pregnant women and the elderly in England. Subsidy is also available for those with high health expenditure for the cost related to eyeglasses and/or contact lenses. In Scotland, universal ophthalmic services are not available under the NHS.

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Countries	Is smoking cessation products covered by basic health insurance?	Coverage by private health insurance	Was the activity subject to HTA?
Australia	Yes, service/advice to stop smoking provided by GPs as part of a general consultation service and claimable from Medicare as part of a routine consultation item. They may also be provided by nurse practitioners. Stop smoking services may also be provided by private health insurance companies, depending on the policies they choose to provide their members. Stop smoking services not subject to health technology assessment. The stop smoking medications would have been subjected to the usual assessments to enable them to be listed on the PBS.	Yes	All medicines including smoking cessation products must be assessed and recommended by the PBAC before being listed on the PBS.
Belgium	Yes, smoking cessation products covered (after one pack or when diagnosed with COPD). Nicotine replacement therapy not covered. Smoking cessation programme is covered. Primary care physicians can obtain pay-for-performance for this. Two drugs partly covered when prescribed in large quantities; Bupropion (100co), Varenicline (140 co). When prescribing in large quantities, the patient must undergo a thorough check-up and fulfil several criteria a priori. Partial reimbursement Bupropion (Category B), Varenicline (Category C). Target population for Bupropion is 35 years and COPD diagnosis, Varenicline minimum 18 years.	One OTC drug: nicotine (if several conditions are met). Two drugs partially covered if prescribed in small quantities: Buproprion (30co) and Vareniciline (28 or 56 co) prescribed by physician. Not reimbursed. Pilot projects through the Fonds Tabac offering reimbursement of nicotine through Social Services or Ligne Tabacstop for non-insured or poor population. No information of coverage by private, supplementary health insurers.	From 2010-2013, follow-up of services reimbursed by health insurance. Decreased volume and amount reimbursed for both Varenicline and Buproprion. Increased volume and amount reimbursed for smoking cessation services for pregnant women and other assured.

Table A.13. Coverage of interventions which can potentially be financed by users: Smoking cessation products

Canada	Yes, coverage varies by province	Varies by plan, PHIs exist	Not available
Chile	No	No	Yes. It resulted in a cost-effective, but has not yet been included
Czech Republic	No	No (Vareniclin)	No
Denmark	No	Not available	Not available
Finland	Yes, medicinal product specific decisions	Not available	Health economic analysis included in the application submitted by the marketing authorization holder.
France	Yes, nicotine replacement therapy is covered up to 50 EUR per year, for pregnant women and those between 15 and 25 years the annual lump sum is 150EUR. Varenicline and Bupropion are not covered	Not available	Not available
Germany	No	Not available	Not available
Hungary	Νο	Not available	Yes, it was rejected because of the high budget impact and to prevent more "lifestyle"-related products applying for health coverage
Iceland	No	No	No
Ireland	Yes	Not available	Not available
Israel	Covered. There is no coverage restriction for nicotine replacement products (Champix/Zyban) but participation in a smoking cessation workshop is mandatory.	Not available	Yes
Japan	Nicotine patch is covered only for those who are diagnosed with nicotine addiction and whose services include the management of nicotine addiction	Not available	No
Korea	Smoking cessation programme is covered.	Community health centres offer medical treatment through anti-smoking programs	Not available
Luxembourg	Smoking cessation programme involving primary care physicians is covered and prescribed drugs officially indicated for	Not available	Not available

	smoking cessation. Minimum 8 months and between first and last consultation. Coverage of 50% of the public drug price with a maximum of 100€. Primary care physicians can obtain pay-for-performance for this.		
Netherlands	Currently, smoking cessation products involve (a combination of): - Short, one-off advices of GP's, medical specialists, clinical psychologists and midwives - More, intense, behavioural focused treatments provided by aforementioned healthcare providers. Pharmaceutical help: nortriptyline is remunerated when prescribed by doctors	Not available	Yes. ZIN estimated the average costs for a smoking cessation programme to be €226 a person in 2010. The effects of the treatment instruments mentioned on the left have been found to be sufficiently cost-efficient, while other (pharmaceuticals like for example Champix) were not thought of as sufficiently valid in their effectiveness.
Norway	No	Not available	Not available
Portugal	Smoking cessation programme is covered.	Not available	Not available
Slovenia	No	No	Not available
Spain	Smoking cessation is not covered	Not available	Not available
Sweden	Prescription drugs can be reimbursed if prescribed in combination with motivating support	No	Not available
Switzerland	Yes, but only 2 drugs only (Vareniclin and Buproprion); nicotine replacement is not covered. High degree of dependence or disease caused by smoking / one treatment course per 18 months	Nicotine replacement: sometimes covered by private insurance (depending from contract)	Yes (societal, legal and ethical considerations worked up in detail)
Turkey	Smoking cessation programme is covered on prescription by physician. Primary care physicians can obtain pay-for-performance for this.	Not available	Not available
United Kingdom	Yes	Not available	Yes, by NICE

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.14 Intervention whose coverage decision can be influenced by social norms: Assisted Reproductive Technologies

Countries	Is assisted reproductive technology covered by basic health insurance?	Is supplementary health insurance available?	Was assisted reproductive technology subject to HTA?
Australia	Yes, both by MBS and PBS. Medicare benefits are payable for assisted reproductive technology (ART) services, including super-ovulated treatment cycles where the services are: •clinically relevant, in other words, generally accepted in the medical profession as being medically necessary for the appropriate treatment of the patient, and •performed in accordance with State and Territory laws. •relevant PBS medicines are prescribed by a medical or nurse practitioner.	No, as the availability of these Medicare funded services p systematic health technology assessment. However, an an service, intracytoplasmic sperm injection (ICSI) was assessNot availableMedical Services Advisory Committee (see MSAC Ref 06 - http://www.msac.gov.au/internet/msac/publishing.nsf/Co 06-1). All medicines must be assessed and recommended PBAC before being listed on the PBS.	
Belgium	 Yes, patient must be of maximum age 43.The treatment is done in a fertility centre recognized of category A or B. Approval by the advisory medical responsible of the health insurance fund. The medication used is divided in three groups, called 'lump sum for medically assisted fertility' (forfaits Medisch Begeleide Voortplanting (MBV)): MBV 1: medication for the IVF itself MBV 2: medication for donation of ovule MBV 3: medication for intra-uterine insemination or for stimulating the follicular development. 	Not available	Not available
Canada	Yes, coverage varies by province	Varies by plan, PHIs exist	Not available
Chile	Yes, for men and women between 25 and 37 years, weighted by parameters established by the literature and experts. Prescribed by physician. Prior authorisation from third-party payer is not required, but the provider negotiates with annual quotas.	Not available	Yes
Czech Republic	Yes, covered for women aged from 18 to 39, based on the recommendation of the authorizing provider in the field of gynaecology	Not available	No
Finland	Yes, fertility medicines are covered.	Not available	Health economic analysis included in the application submitted by the marketing authorization holder.

France	Yes, covered for women with a male partner up to age 43 and 4 attempts of IVF.	Not available	Not available
Greece	Yes, covered for women up to 50 years of age and up to four integrated efforts	Not available	Not available
Hungary	Yes, ART is covered for maximum 5 attempts per patient. Two separate physicians have to declare that it is unlikely for the patient to have a healthy baby the natural way, female patient has to be within reproductive age (Degree No. 30/1998 VI.2). NM of the Ministry of Welfare on the Rules of Special Procedures for Human Reproduction and on the Detailed Rules of Use and Freeze Storage of Reproductive Cells and Embryos Decree No. 47/1997 (X.II.17). NM of the Ministry of Welfare on Infertility Treatments which can be utilized in the Frame of Compulsory Health Insurance.)	Not available	Not available
Iceland	Yes, however, no coverage for first treatment, partial coverage after the first treatment	Not available	Νο
Israel	Diagnosis and treatment of infertility are covered and they include tests for diagnosis of infertility and for the need for assisted reproductive technology, infertility treatment, artificial insemination, including male factor treatments, and IVF for the first two children for a couple without common children, and for a woman who wishes to be a single mother. Pre-implantation genetic diagnoses for cases of severe genetic diseases are also covered.	Supplementary health insurance schemes cover IVF treatments for 3rd and 4th children, and ovum donation from overseas (limited reimbursement).	Yes
Japan	No	Not covered. Subsidies are available in some municipalities but the financial support varies by region. The cost could be deducted for tax declaration.	Νο

Korea	No (under discussion)	Infertility Support Project offer funds to low income couples	Not available	
Luxembourg	Yes, prior authorisation from CMSS is mandatory. Women must be aged under 43, 4 attempts, and no reimbursement after vasectomy or tubal litigation.	Not available	Not available	
Mexico	No	Not available	Not available	
Netherlands	Yes, but assisted reproductive technology is only remunerated for: - Women until the age of 43 - Ovulation induction, artificial (donor) insemination, intra-uterine insemination are remunerated completely - In vitro fertilization and intra-cytoplasmic sperm injection are remunerated a maximum of 3 attempts per pregnancy	Not available	Yes. In 2012 also a report was presented to the Minister of VWS which described methods to save costs from assisted reproductive technology usage.	
New Zealand	Not available	Not available	Not available	
Norway	Yes, partly covered as fertilisation drugs and consultations are paid out-of-pocket.	Not available	Not available	
Poland	Covered excluding in vitro procedures. Medical indication	In vitro procedure is covered within the ministerial health according to the conditions specified in the programme.	It was not the subject to health technology assessment.	
Portugal	Covered. Coverage conditions are defined by the General Health Directorate (DGS). There are two types of approved group treatments and a patient/couple is enrolled in each one according to age limits (41 years and 365 days for the Group I and 39 years and 365 days for Group II), number of children together, number of treatments already tried (there is a limit of 3 groups of treatments per couple in Group II). A number of accessibility and quality indicators are contracted with each recognized treatment centre.	Not available	Not available	
Slovenia	Yes, medical indications -infertility, limited number of cycles and limited age.	No	Approved by the Health Council (MoH)	
Spain	Yes, when prescribed by physician plus criteria such as the age and the maximum number of cycles. Additionally, the following factors are	Not available	Not available	

	 influencing coverage decision: Influence of male age in the success rate of pregnancy in ART Sperm washing in ART Pre-implantation Genetic Diagnosis Gamete intrafallopian transfer Evidence of the effectiveness and safety of cryopreservation gonadal tissue as a procedure to preserve fertility 		
Sweden	Yes, pharmaceuticals are mostly within reimbursement system, other health care activities might differ	Not available	Not available
Switzerland	Yes, Insemination: 3 course per pregnancy, artificial insemination: yes, IVF: no.	IVF: probably no	Not available
Turkey	Yes, SSI pays the condition of the couple does not have children, could not get positive results from other treatments that have been tried last three years, and this situation must be documented by medical board within hospitals.	Not available	Not available
United Kingdom	Yes, when clinical decision by physician	Not available	Yes, by NICE

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire Table A.15. Coverage of interventions which are at the frontier between health and cosmetics: Breast reconstruction after mastectomy

Countries	Is breast reconstruction after mastectomy covered by basic health insurance?	Is supplementary health insurance available?	Was breast reconstruction after mastectomy subject to HTA?
Australia	Medicare benefits are payable for breast reconstructions after mastectomies, where the services are: -clinically relevant, in other words, generally accepted in the medical profession as being medically necessary for the appropriate treatment of the patient, and - performed in accordance with State and Territory laws. See http://www9.health.gov.au/mbs/search.cfm?q=mastectomy&sopt=S	Not available	No as the availability of these Medicare funded services pre-dates mandatory health technology assessment.
Belgium	Yes, it is covered when the following criteria are fulfilled: The breast was fully amputated because of a tumour, a mutilating intervention or some congenital affection of deformation. o In some cases approval is necessary of the advising doctor of the sickness fund. • Extern breast prostheses and/or accessories. The material is recognized by the health insurance authorities (INAMI/RIZIV). • Arm sleeve or glove. o If a lymphedema occurs after a total or partial amputation of the breast where the armpit glands were also removed. o For individually adapted material: approval is necessary by the advising doctor of the sickness fund.	Not available	Not available
Canada	Yes, conditions varies by province	Not available	Not available
Chile	Yes, anyone who is prescribed by doctor, because it's covered by Plan GES. Depending on the ability to offer this service to all women requiring surgical intervention is delivered. The third party payer does not authorize each case, but the provider negotiates with annual quotas.	Not available	No.
Czech Republic	Yes	Not available	No
Finland	Varies by region, decisions made by local, autonomous authorities	Not available	Not available
France	Yes	Not available	Not available
Hungary	Yes, when mastectomy was done because of medical condition related surgery	Not available	Not available
Iceland	Yes, this is a normal part of health insurance coverage		No
Israel	Yes, covered for breast reconstruction post malignancy.		No
Japan	Yes, when following a diagnosis of breast cancer (but not for preventive purposes)		No

Korea	No (under discussion)	Not available	Not available
Luxembourg	Yes. A prior authorisation from CMSS is mandatory. The patient must be aged 18 years or older. The dossier submitted must contain support from a surgeon or a doctor specialised in gynaecology or obstetrics. The patient may not have benefited from a breast reduction before.	Not available	Not available
Netherlands	Yes, the basic health insurance covers breast reconstruction after mastectomy. Insertion of breast prostheses is covered. Autologic fat transplantation techniques for breast reconstruction will be covered under conditions from 2015 on, to test the validity and effectiveness of this technique.	Not available	The conditional coverage of autologic fat transplantation techniques for breast reconstruction was approved, because it might offer savings compared to breast prosthesis techniques. During a period of maximum 4 years data will be gathered to test whether this is the case.
Norway	Yes, but covered only for patients where breast reconstruction is recommended. It is also included in guidelines for breast cancer.	Not available	Not available
Poland	It is covered in medically justified cases.	Not available	Not available
Portugal	The coverage is determined by the physician	Not available	Not available
Slovenia	Yes, medical indications after mastectomy	No	Defined in Regulation of CHI
Spain	Yes, medical indications	Not available	Not available
Switzerland	Yes, and new from 2015: also reduction of contralateral breast if appropriate	Not available	No
Turkey	Yes	Not available	Not available
United Kingdom	Yes, clinical decision by physician	Not available	Not available
United States	Medicare: Yes	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Questionnaire

Table A.16. Coverage of interventions which are at the frontier between health and cosmetics: Orthodontics

Countries	Are orthodontic treatments in children covered by basic health insurance?	Is supplementary health insurance available?	Was orthodontics treatment in children subject to HTA?
Australia	No.	Not available	Not available
Belgium	Yes, maximum age of 9, only covered for correction of: frontal and lateral cross bite, frontal and lateral duress bite, position of incisor as prevention of anterior traumata, lack of space during the changing of teeth.	Not available	Not available
Canada	Yes, covered in some cases in some provinces and territories and coverage conditions vary by region.	PHIs are available but the coverage varies by plan.	Not available
Chile	Νο	Yes, by some private health insurers	No
Czech Republic	Yes, limited or partial coverage depending on a specific model of the aid based on a recommendation by physician	Not available	No
Finland	Yes, covered for children under 18 years	Not available	Not available
France	Yes, covered for children up to 16 and up to 6 semesters.	Not available	Not available
Greece	Yes	Not available	Not available
Hungary	Yes, prescription of physician, depending on the medical condition (for example: facial malformation, cancer, trauma)	Not available	Not available
Iceland	Yes, covered by low fixed sum for each case	Not available	No
Israel	Yes	Limited coverage by supplementary private health insurance schemes.	Yes, for congenital facial/dental defect treatments
Japan	Yes, only limited to care before and after occlusal abnormality or jaw deformity (only restricted to those which require surgeries such as jaw disarticulation) which are designated by the Minister of Health, Labour and Welfare	Not available	Νο

Korea	No	Not available	Not available
Luxembourg	Yes, a prior authorisation except for two services from the CMSS is mandatory. Dental impressions are only reimbursed three times in five years, not exceeding once a year. The treatment has to be performed before the age of 18.	Not available	Not available
Netherlands	No, it is normally not covered. Orthodontic treatments in children are only remunerated if the parents are insured for dental care and a child has very severe developmental/growth disturbances of the tooth/jaw/mouth, for which treatment of other disciplines than dental care is necessary.	Some health insurers do offer osteopathy remuneration in supplementary private health insurance schemes. The amount of services remunerated and the changes in premium differs between insurers.	Νο
Norway	Yes, covered mainly for patients up to 20 years, based on specific criteria, financed by a combination of State remuneration system and patient payment.	Not available	Not available
Poland	Yes, covered for children up to 12 years old, orthodontic treatment with removable appliances	Not available	Not available
Slovenia	Yes	No	Defined in Regulation of CHI
Spain	No	No	Not available
Switzerland	No	Yes, covered by invalidity insurance for children and adolescents up to 20 years.	Νο
Turkey	SSI pays 1/3 of the cost of orthodontic treatments for those under 18 years of age.	Not available	Not available
United Kingdom	Yes, when clinical decision is made by physician	Not available	Not available
United States	Medicare: No	Not available	Not available

Note: The table only includes information from responding countries. Source: 2014 OECD Health Benefit Basket Survey

Table A.17.	Coverage of	dental	care and	prosthesis
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Countries	Is dental care and/or dental prosthesis covered by basic health insurance?
Australia	Not covered and no Medicare subsidies for private dental services but covered by some PHIs.
Austria	Covered.
Belgium	Covered.
Canada	Dental care and prostheses are not typically covered unless deemed medically necessary but for certain groups (e.g., low-income residents and seniors), most provincial and territorial governments cover a range of supplementary benefits related to dental care, that are not covered under the Canada Health Act. Individuals and families who do not qualify for publicly funded coverage may be covered for dental care under an employment-based group insurance plan, or buy private insurance.
Chile	Patients insured under FONASA are covered for dental care and prosthesis while publicly insured patients with free choice of provider are not. People insured with one of the private insurance companies of the ISAPOREs, also generally do not have coverage for dental care or prostheses, but insurers often offer preferential prices following certain agreements. In addition, the GES Programme (Explicit Health Guarantees) includes the coverage of dental care to some populations, such as children below age 6, pregnant women and older people age 60 and over.
Czech Republic	Covered but a range of covered dental services is limited. For some types of dental procedures, patients must obtain permission from a review doctor working for their health insurance fund in order to qualify for coverage.
Denmark	Prostheses are covered for children. Dental surgery and treatment and prostheses are covered for patients carrying certain diseases or in particular need of treatment (nursing home and long term hospital patients). Prosthesis is generally not covered although there is some coverage for persons not developing teeth as they grow up and for persons having lost their teeth traumatically as a consequence of certain diseases.
Estonia	Dental care is covered for the insured over 63 years of age and persons eligible for an old-age pension. Dental care is also covered for persons with a greater need for dental treatment because of a particular condition, persons eligible for a work incapacity pension, pregnant women and mothers of children up to 1 year of age.
Finland	Covered.
France	Covered.
Germany	Covered and include a wide range of services such as conservative dental treatment, surgical treatment, x-rays, crowns, bridges and prostheses. Orthodontic is also covered.
Greece	Covered.
Hungary	Covered.
Iceland	Dental care and prostheses are covered for children, seniors and those with vulnerable medical conditions.

Ireland	Oral examination and emergency dental treatment including extractions and complex treatments are covered and denture repairs are covered where justified as an emergency treatment. Oral examination is limited to once every calendar year and fillings up to 2 fillings per year. Wider range of dental treatment is covered for high risk patients i.e. those with special needs and those with greater clinical needs and for instance, dentures are covered subject to approval based on clinical necessity or emergency circumstances. Some PHIs offer plans that include emergency and non- emergency dental care.	
Israel	Dental care and prostheses are covered for children under 12 and people with vulnerable medical conditions. PHIs are also available	
Italy	Emergency care for dental infections is covered and so as dental care and prostheses for children up to 16. Dental care and prostheses are also covered for designated groups of people with particularly vulnerable conditions (e.g. serious cardiovascular diseases, drug addiction, disabilities and rare diseases) and the low income. Some regions and local health authorities cover extra dental and prostheses services.	
Japan	Covered and include a wide range of services such as conservative dental treatment, surgical treatment, x-rays, crowns, bridges and prostheses.	
Korea	Dental care is covered and prosthesis is covered for the elderly	
Luxembourg	Covered.	
Mexico	The public health insurance fund Seguro Popular with the coverage of about half of the population cover certain dental treatments but not prostheses. Social Security does not cover dental care.	
Netherlands	Basic dental care is covered but the coverage is restricted to specialist dental care in hospitals which include prostheses. Dental care is covered up to age 22 and specialist dental care and prostheses are covered for older people. PHIs are also available.	
New Zealand	Dental care is covered for children under 18. Emergency dental treatment at hospitals or with approved dental contractors is covered for low to middle income population who are entitled to Community Services Card. PHIs are also available.	
Norway	Surgical interventions and cleansing in the case of gum disease/periodontitis are covered. Dental care and prostheses are covered for children up to age 20, patients in nursing homes, persons who receive health care at home and those with certain medical conditions. Orthodontic treatment can be also covered based on the condition. But prosthesis is generally not covered although there is some coverage for persons not developing teeth as they grow up and for persons having lost their teeth traumatically as a consequence of certain diseases or accidents.	
Poland	Covered but a range of covered dental services is limited. For example, one lower and one upper acrylic prosthesis is covered every five years. But orthodontic is also covered for children up to 18. Prosthesis is generally not covered although there is some coverage for persons not developing teeth as they grow up and for persons having lost their teeth traumatically as a consequence of certain diseases.	

Portugal	Dental care is covered for children up to 16, pregnant women and people living with HIV/AIDS. Dental care and prostheses are also covered for low income elderly but they are covered for dental prosthetic every three years. Each occupation- or profession-based health insurance schemes called subsystems defines its own list of eligible dental treatments.
Slovenia	Covered.
Spain	 The following treatments are covered: Treatment of acute odontologic processes Preventive examination of oral cavity in pregnant women Preventive and assistance measures for children (application of topical fluoride, obturations, sealing of cracks) Dental implants for patients undergoing oncological processes that imply loss of teeth or congenital malformations
Sweden	Covered.
Switzerland	Dental care is covered only in very exceptional cases, e.g. if dental treatment is pat of another treatment, or if dental problems are caused by another disease).
Turkey	Covered and services include inpatient and outpatient oral health care, such as oral and dental examinations, diagnostic tests and procedures, medical interventions and treatments after diagnosis, tooth extraction, conservative dental treatment and endodontic treatment, follow-up services, oral prosthesis and emergency services. Orthodontic is also covered for children up to 18 years old.
United Kingdom	Dental care and prostheses are covered for children, seniors, the low income and pregnant women in England but in Scotland, dental examinations and treatment are covered.
United States	Most Medicare and Medicaid programmes include dental care and prostheses and dental care are also covered depending on health insurance funds.

Note: The table only includes information from responding countries.

Source: 2012 OECD Health System Characteristics Survey

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