

Rapid Review 8

Assistive Devices: Regulation and Coverage in five Euro- pean Countries

A Rapid Review Prepared for Converge3

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October 2018



This report was produced by SiTi – Berlin Institute for Health Care Management the North American Observatory on Health Systems and Policies at the request of the Converge3.

Converge3 is a policy research centre based in the Institute of Health Policy, Management and Evaluation at the University of Toronto, that focuses on integrating health, economic and equity evidence to inform policy. The Centre is funded by the Ontario Ministry of Health and Long-Term Care and includes multiple partner organizations, including Li Ka Shing Knowledge Institute at St. Michael's Hospital, McMaster University, Ottawa Hospital Research Institute, Institute for Clinical Evaluative Sciences, Health Quality Ontario, and Public Health Ontario.



The views expressed by authors are not intended to represent the views of the Converge3 or any of the other partners of the North American Observatory on Health Systems and Policies.

Suggested citation:

Panteli D., van Ginneken E., Fuchs S., Henschke C., Hjortland M., Kroneman M., Oliva G. (2018). Assistive Technologies: Regulation and Coverage in five European Countries. Toronto: North American Observatory on Health Systems and Policies. *Rapid Review* (No. 8).

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Toronto, ON M5T 3M6

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**Assistive Technologies: Regulation and Coverage in five European Countries
Draft Report, May 2018**

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Background

In the Member States of the European Union, approximately 44 million people aged 15 to 64 have reported a disability. In 2011, about 26% of people aged 16 years or over declared health-related, long-term limitations in usual activities (8.2% severe, 17.5% moderate disability). The health needs of disabled people vary. Overall, people with disabilities have a poorer health status than the general population and face discrimination and significant barriers to exercising their rights; they remain one of society's most vulnerable groups (European Commission, 2015).

The primary purpose of assistive technologies (ATs) is to maintain or improve an individual's functioning and independence to facilitate participation and to enhance overall well-being (put differently, in the official definition for this work: ATs encompass “any item, piece of equipment, or product, whether acquired commercially, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities” - United States of America Assistive Technology Act 2004).

ATs can be seen as a factor facilitating the life of disabled people by reducing certain barriers, especially in the field of employment. In fact, access to assistive devices and technology derives from the basic principles of human rights, such as dignity, autonomy, equality, non-discrimination, participation and inclusion (EPRS, 2018a).

The UN Convention on the Rights of People with Disabilities (CRPD), adopted in 2006, is legally binding for both the EU and its Member States. It affirms that assistive technologies are essential to enable persons with disabilities to live independently and to participate fully in all aspects of life. It also strongly points out that their affordability and accessibility are necessary to ensure equitable access.

ATs are usually provided through the social security or public health systems of the Member States; the EU adopts a coordinating role. This often poses a portability challenge for people with disabilities in the context of the EU's free movement of citizens. As the prevalence of disability increases with age, demographic change necessitates a closer look at how ATs are regulated and covered at the national level. The aim of this work is to explore modalities of regulation and coverage of ATs in a meaningful sample of European countries and highlight potential avenues for supranational collaboration and knowledge exchange.

Methods

Country sample

This work focuses on five European countries, namely Germany, Italy, the Netherlands, Norway and the United Kingdom. The sample was chosen to include both tax-financed (National Health Service-type) and health-insurance based systems as well as countries with a variable degree of decentralization concerning the provision of health care in general and ATs in particular. Table 1, below, shows relevant characteristics of the health systems in the selected countries.

Table 1: Characteristics of the health systems in the country sample

					
	Germany	Italy	Netherlands	Norway	UK
Health system financing (main)	Compulsory SHI	tax-based (National Health Service)	Compulsory SHI	tax-based (National Health Service)	tax-based (National Health Service)
Universal coverage	Yes	Yes	Yes	Yes	Yes
Role of private health insurance	Substitutive; Complementary (excluded services, some cost-sharing); Supplementary (convenience).	Complementary (excluded services, cost-sharing); Supplementary (convenience).	Complementary (excluded services, cost-sharing); Supplementary (convenience).	Mainly supplementary (faster access, provider choice).	Supplementary (faster access, convenience).
% Population with private health insurance schemes	8.8% (substitutive, 2015)	8% (2015)	84% (2015)	9% (2015)	10.5% (2015)
Definition of (minimum) benefit catalogue	Self-governance	Government	Government	Parliament (no explicit catalogue)	No explicit basket
THE as a % of GDP	11.2% (2014)	9.1% (2014)	10.8 (2015)	9.9% (2015)	9.9% (2014)
THE per capita	USD 5119 (2014)	USD 3207 (2014)	USD 5227 (2014)	USD 6112 (2015)	USD 4094 (2014)
Financial protection for OOP	Annual cap at 2% of income (1% for qualified patients with chronic conditions)	Exemptions for certain chronic conditions and severe disabilities	Annual deductible structure of cost-sharing; beyond that, cost-sharing applies only to certain types of services	Annual OOP caps (general: ca. USD 270); possible tax deductions and/or benefits in kind	Exemptions for certain conditions and patient groups (low-income, under the age of 18)

Source: Commonwealth Fund 2018

Analytical framework

We adopted the analytical framework prepared by colleagues at the University of Toronto for their work on the interjurisdictional analysis of AT programs; this includes four domains:

1. **Mandate of the programs:** what is the governing legislation and who administers the program (e.g., provincial government, regional authorities, a combination of government and charitable organizations)?
2. **Eligibility criteria:** who is eligible to benefit from these programs (e.g., age, health conditions, assessments, living arrangements, financial status, access to private funding)? and where does the administrative burden fall?
3. **Devices Included:** What types of devices are covered under the program (breakdown of ATs into 4 distinct categories: mobility aids; household aids; respiratory aids; and audio, visual, and communication aids)? How are inclusion/exclusion decisions made?
4. **Coverage:** what are the mechanisms for funding these devices (full or partial coverage, loaned); what is the service/product support approaches (rented devices, reimbursement strategies, deposits); and how are the funding approaches determined?

We do not focus separately on ATs covered in the context of employment or education in this draft: where of particular relevance, a short reference is made in the text.

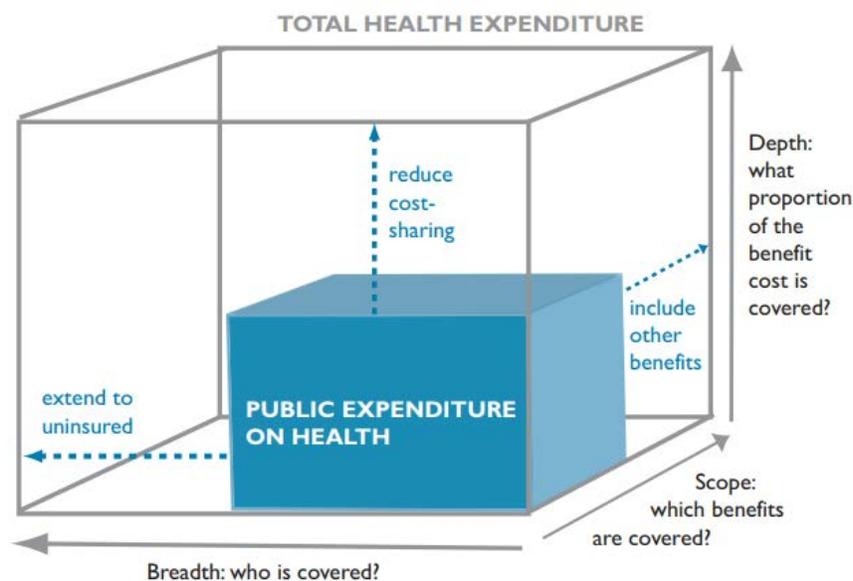
We also adopted the operationalization of the definition for ATs used by the same working group. This includes 4 distinct categories of ATs where the cost of purchasing is expected to be high:

- Mobility aids include such things as wheel chairs, walkers, crutches.
- Household aids refers to such things as hospital beds, stair lifts, bathroom devices, transfer lifts.
- Respiratory aids refer to such things as continuous positive airway pressure (CPAP) machines, and oxygen support.
- Audio, Visual, and communication aids include bone anchored hearing aids, adaptive telephones, reading and writing devices.

Within the given focus of this work as shown in the operationalization above, the adopted framework corresponds to the three dimensions of coverage as first proposed in two publications by Busse et al. (2007) and subsequently adopted by the World Health Organization in their 2010 World Health report to describe universal health coverage (see Figure 1). The findings section

looks at terms of eligibility (who is covered, *breadth* of coverage), which ATs are covered (what is covered, *scope* of coverage) and the level of cost-sharing required (proportion of the AT costs covered, *depth* of coverage).

Figure 1: Dimensions of coverage



Source: WHO 2010

Evidence generation

The evidence generation to answer these questions was tackled in a two-step approach, combining publicly available information with country expert consultation. This was repeatedly validated as an efficient and robust approach during previous work of the European Observatory on Health Systems and Policies (e.g. Panteli et al. 2016). Thus, in a first step, multiple sources were used to put together information on the aspects delineated above. National regulatory documents as well as published and grey literature were used to identify and explore relevant strategies at national level, building on the Department's existing work on medical devices (e.g. Henschke 2012, Fuchs et al. 2016, Fuchs et al. 2018). Previous publications of the European Observatory on Health Systems and Policies, particularly in the Health Systems in Transition (HiT) series, were identified for each included country and the Health Systems and Policy Monitor (www.hspm.org) was searched for relevant updates. Subsequently, collaborators from the selected countries were asked to verify and expand on the identified information.

Overview of results

Information on the regulation and coverage of ATs in included countries is presented briefly below and organized thematically following the analytical framework detailed above.

Mandate, Alignment and Accountability

Many ATs are classified as medical devices and are thus covered by the Medical Device Directives (and the succeeding Medical Device Regulation, adopted in 2017); these apply for all EU Member states as well as countries in the European Economic Area, such as Norway. A prerequisite for such technologies to enter the European market has been the European Conformity (Conformité Européene [CE]) marking. This is assigned by one of the Notified Bodies – an entity under private law that has been accredited by a EU Member State – to ensure that the device follows the applicable regulation; the criteria for obtaining the CE mark vary by risk level of the device in question. However, obtaining the CE mark does not require a profound demonstration of effectiveness or safety based on scientific clinical data for any device type. As assistive devices often fall into lower risk classes, a lack of robust evidence regarding clinical effectiveness at the premarket stage is still the norm. Even the newly passed EU regulation on MDs (Medical Device Regulation 2017/745, MDR), does not adequately address this issue.

Once the CE mark has been granted, European countries use different ways to define access to assistive devices and their funding and reimbursement.

In **Germany**, the basic entitlements of the population in the social health insurance (SHI) system for receiving assistive devices are defined in the Social Code, Book V (SGB V). The Social Code regulates rules for providing and financing social services (including health care) at the federal level. Additionally, the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), the highest decision-making body in the self-governance of insurers, hospitals, physicians and dentists, is responsible for determining the benefit package by issuing relevant directives. In this context, it also ensures the adequate, expedient and cost-effective provision of ATs for the insured population (Busse et al. 2005). The directive on assistive devices broadly defines the situation in which patients are entitled to AT benefits and limits the prescription of ATs to the following cases: ensuring the success of medical treatment, preventing potential/imminent health damage, preventing the health endangerment of a child, and avoiding or reducing the risk of long-term care. The directive also establishes the fundamentals of a benefit catalogue for assistive devices. This

includes a list of assistive devices subdivided into 33 categories with individual products that can be provided at SHI expense (Busse and Blümel 2014). The Federal Association of Sickness Funds administrates this quasi-positive list and regulates quality requirements. If a certain device is not included in the SHI benefit package, sickness funds decide on a case-by-case basis whether to provide it. Separate provisions for the inclusion of people with disabilities and the provision of ATs apply under employment law. The German constitution was amended to include a provision against disadvantaging persons with disability (*“No-one should be disadvantaged because of their disability”*, Article 3).

In Italy, the provision of ATs is part of the National Health System (NHS). This is set out in Ministerial Decree n. 332 (27 August 1999). The Decree sets the rules that explain in detail who is entitled to an assistive device and under which conditions. Provisions for the protection of persons with disabilities are anchored in the Italian Constitution; Law 102/2009 further stipulates that if the working capacity of a person is reduced by at least one third (33%) due to chronic or permanent illness (physical, mental or intellectual), that person can receive benefits in financial support and in kind; these benefits depend on the extent of disability. The decentralized nature of the health system (Ferre et al. 2014) means that regional health authorities have the main responsibility for organizing the provision of ATs while local authorities are tasked with their delivery to the residents in their catchment area, often supplemented by charities and patient organizations. Schools collaborate with local health authorities regarding the provision of ATs for educational purposes while the national system for insurance for labour accidents is involved where applicable. ATs along with other products covered by the NHS are listed in the tariff catalogue (*“nomenclature tariffario”*). To be covered, they need to be prescribed by a physician with a relevant specialty (Cullen et al. 2012).

In **the Netherlands**, the regulatory framework for ATs consists of several (sometimes overlapping) insurance schemes and programs:

- Health Insurance Act (ZVW): a national program for curative care carried out by competing social health insurers;
- Social Support Act (WMO): the main legislation covering AT for home/ independent living and organized and implemented by the municipalities;
- Long Term Care Act (Wlz): the national program for long term care, which covers long-term inpatient care (in nursing homes). The scheme is carried out by regional care offices (zorgkantoren), which are run by the dominant care insurer of the respective regions;

- Act for Employment and Income According to Employment Capacity (WIA): The Employees Insurance Administration Office (UWV) has a central role in relation to AT for work/employment.

Everyone is mandated to purchase health insurance under the ZVW and a large number of private insurers compete on the market; those on low incomes receive tax subsidies towards their premiums. The benefits under the WMO and Wlz are accessible to all. The Social Support Act of 2015 stipulates that people should be compensated for their inability to participate in society, supported by municipalities. This includes, for instance, domestic care, transport facilities, aids such as wheelchairs and house adjustments. Municipalities must first explore the opportunities for applicants to take care of themselves, with the help of their social network. If these are considered insufficient, publicly funded support will become available; recipients may be asked to share in the cost on the basis of their income (Kroneman et al. 2016). Certain types of ATs are reimbursed through (private) health insurance.

In **Norway**, the provision of assistive devices is based on individual rights and covered by the Act on Social Security (or National Insurance Act, *Lov om folketrygd*). They must be both necessary and appropriate with regard to improving the user's ability in performing activities and participating in daily life. Local authorities have the fundamental responsibility for health care, social and rehabilitation services, including the provision of assistive devices. There are 18 regional assistive technology centres covering the entire county and serving as a referral system. They give guidance to the local authorities and other relevant stakeholders aiming to ensure that users receive the same quality of care regardless of where they live. ATs are purchased, adapted/adjusted and delivered to the local authorities by the assistive technology centres. In this context, procurement framework agreements are made with various dealers of assistive devices (NAV 2017). From the regulatory perspective, the Working Environment Act (*Arbeidsmiljøloven*, 2005; § 4-4) further cements entitlements to AT; it stipulates that it is the responsibility of the employer to facilitate equal workspace access for all employees and provide ATs accordingly.

In the **United Kingdom**, there are substantial differences among the four countries (England, Scotland, Northern Ireland and Wales). Broadly speaking, responsibilities for AT provision fall within the scope of both the health services (National Health Service - NHS) and local authorities as part of social services. The NHS covers ATs for mobility, hearing and vision aids and communication aids, as well as orthoses and prostheses, while local authority social services departments are mainly responsible community equipment services. NGOs are also key players in providing consolation services to patients in need of ATs. The NHS is a tax-funded system which

covers all residents, largely free at the point of use. It was created with the National Health Service Act of 1946, last modified by the National Health Service Act of 2006 and the Health and Social Care Act of 2012. The scope of benefits covered by the NHS is not a priori set out in legislation. Rather, it provides services “to such extent as [considered] necessary to meet all reasonable requirements” (Mason 2005). However, the promotion of equality and fairness - including the right to not be discriminated against based on disability - are clearly outlined in its guiding principles, as is the importance of value for money and sustainability (see also the NHS Constitution of 2015).

Table 2: Mandate and Accountability

Country	Category	Governing Legislation	Regionally Administered	Flexibility of Individual payers	Substantial role of charities
Germany		SGB V/ IX	no	yes	no
Italy		Law 104/92 MD 332/1999	yes	n.a.	yes
Netherlands		SSA	locally	yes	no
Norway		ASS	Locally (regional re- ferral system)	n.a.	no
United Kingdom		NHS Act	Yes / local	n.a.	Yes

n.a.: not applicable

Eligibility

A commonality among included countries is that the eligibility for receiving ATs at the cost of the statutory health system relies on an assessment of the individual needs of the patient, mirrored in a prescription by a health professional competent in the area of the person’s disability. This usually needs to be further authorized by the instance responsible for providing and/or covering the devices. For example, **in Italy**, the local health authority of residence has to document confirmation of eligibility so that the patient can receive ATs. While age or income do not seem to be a prominent influencing factor in a direct way, different eligibility criteria governing ATs used in the context of employment or education mirror the consideration of separate patient groups. Means testing is used **in the UK** in the context of locally determined eligibility for related services provided

at the community level – those who do not meet them have to purchase AT privately, potentially with NGO assistance. Local authorities (or councils) are responsible for that determination (NHS 2018a). The basis of distinction between AT being provided by the NHS or through council funding lies with its application for healthcare or social care purposes. Certain adults with long-term complex health needs are eligible for “NHS continuing healthcare”, that is free social care arranged and funded solely by the NHS. Entitlement is determined following an assessment by a multidisciplinary team organized by NHS Clinical commissioning groups (CCGs), which commission local health services (NHS 2018b). The needs and provided support of individuals eligible for NHS continuing healthcare are reviewed at least annually after the initial assessment, among others to determine continued eligibility.

In **Germany**, all individuals under social health insurance are eligible for assistive devices that are necessary to ensure success of treatment and prevent or compensate disabilities unless these devices are consumer applications of daily use. Especially in the case of expensive technologies, patients must submit an application for the provision of an assistive device to the sickness fund along with the prescription, which must attest the medical need for the device. In addition, the provider of assistive devices (i.e. persons or institutions authorized to supply assistive technologies, e.g. medical supply stores or orthopedic workshops) must submit a general cost calculation to the sickness funds. However, the sickness funds can obtain expert advice concerning a patient’s application. In this case, the SHI Medical Review Boards monitor the applicant’s medical need for an AT. Finally, sickness funds must approve the application to guarantee the provider receives remuneration according to the contracts, agreements or reference prices. The criteria for eligibility are broadly defined in the Social Code, Book V (see above). Specific restrictions apply to certain AT categories (e.g. vision and hearing aids, see below). Review of eligibility is triggered through a change in diagnosis certified by a medical professional.

In **the Netherlands**, eligibility requirements reflect the complexity of the system described in the previous section. Under the ZVW, the insured or (para)medical professional treating the insured person makes a request for a AT. The Zorginstituut has issued a document describing exactly which ATs are under the Zvw and which under the Wmo. Generally speaking, short term use (less than 6 months) falls under the Health Insurance Act (e.g. for wheelchairs, hoymers etc), while long term use under the Social Care Act. In part, this mirrors practices in the UK, described above. The insurer decides on the basis of their expertise, policy and the case description whether the application for AT is eligible. Under the WMO, a resident of the municipality seeking services must

first go to the WMO “window”, which can either be a website or public facility. Qualified WMO personnel (e.g. OTs) make an initial intake assessment in order to identify the nature of the participatory need. Where necessary a home visit can be made to assess the physical and social environment, personal factors, and other background information. A second opinion can be requested in complex cases. The Wlz only covers AT for individuals living in nursing homes. Those living at home will have to go to their municipality to receive ATs under the WMO. Eligibility is determined by the Centre for Needs Assessment (CIZ) but the responsibility of purchasing AT is delegated to care offices (Zorgkantoren). In general, the systems operate to avoid overlap or duplication, but people can make use of both regulations simultaneously but not for the same type of AT. A power wheelchair could be provided by the municipality but a robot arm attached to the wheelchair would be provided by the health insurance. The government sponsors a website called hulpmiddelenwijzer.nl where 457 different medical devices are listed. It contains information on the device, its cost and whether they are covered by any of the regulations.

In **Norway**, the definition of eligibility contains the aspect of permanence: persons whose functional capacity is impaired for more than two years are entitled to receive financial support for ATs under the national insurance scheme. Those with a temporary need for assistive devices must apply for financial support elsewhere, usually through the local authorities (NAV 2017). In any case, eligibility is determined by trained personnel (usually occupational therapists or physiotherapists) are responsible for identifying and assessing user needs, recommending and providing assistive devices, as well as following up the users’ situation in daily life.

Table 3: Eligibility Criteria

Country	Category	Individual needs assessment	Age	Income	Disease	Long-Term Condition	Separate regulation for entitlement based on employment or education
Germany		x					x
Italy		x					x
Netherlands		x					x
Norway		x				x	x
United Kingdom		x		x		x	x

Devices Included

All countries in the sample cover the majority of ATs as operationalized for this work (see Methods section and Table 4, below). The broadest coverage is perhaps **in Norway**, where requests cannot be denied even under budgetary constraints and ATs for sport are also covered. As an example in this direction, since 2014, pupils with reading and writing impediments, and dyslexia, can apply every four years for a computer grant of approximately USD 400 (NAV 2018). **Italy's** positive list includes most of the typical ATs encompassing prosthetic, orthotic, orthopaedic and hearing equipment as well as wheelchairs, walkers, beds, hearing aids and incontinence aids. Communication devices and those for learning and cognitive development are included in the first list of the Tariff Catalogue ("Nomenclatore Tariffario), but are not addressed to the same extent. This is in part related to the relatively lax pace of updating the catalogue (the last revision of the Tariff Catalogue was on 12 January 2017, while the one before than was on 27 August 1999). Local authorities can decide to enable coverage to ATs not included in the national positive list.

Once again, **in the Netherlands**, the scope of devices covered depends on the stream of coverage, but overall all devices in the operationalization shown in Table 4 used to be accessible to citizens. The insurance companies are obliged to offer a standard package of cover ('basispakket'). The types of AT which are covered are defined by ministerial regulations: in this context, the ATs are not listed individually, but rather described functionally: e.g. there is 'material for absorbing urine' instead of 'diapers'. A range of ATs are in this benefit package and eligible for funding through insurance. Each municipality has its own regulations on what AT can be provided and its own budget. An agreement negotiated between the Ministry of Social Affairs, disability organisations and the Association of Dutch Municipalities aims to encourage uniformity in what is provided across all municipalities. However, differences between municipalities do occur in practice. AT provided under the WMO generally includes mobility/walking supports such as wheelchairs, scooters, adapted bicycles (also shared taxi services when possible) and home adaptations e.g. raised toilet seats, adapted bathrooms, stair-lifts (also coverage of costs for moving to an adapted home). Recent developments have led to the exclusion of certain ATs in the included categories: for example, walkers, crutches, special chairs and glasses are not reimbursed anymore by any of the schemes. This falls under the general reimbursement logic within the Dutch insurance system, whereby services (and technologies) which should be easily affordable by individuals are not subsidized by the public health care system. Another issue with accessibility concerns waiting times. Among Dutch AT users, many complain about waiting times for approval

of their entitlement (30%) but also delivery of the device once it has been approved (39%). However, the biggest problem seems to be waiting for the repair or replacement of ATs already in use (mentioned by 47%) although temporary replacement is available in most cases (Van Harten & Toersen 2015).

Looking at the financing aspect of reimbursed ATs, **in Germany**, the Federal Association of Sickness Funds is responsible for selecting which ATs can be submitted to the reference pricing system and for defining reference price limits for each group. Patients have to pay the difference between this price limit and the selling price of the device (see also next section on coverage). Currently reference pricing applies to ATs including hearing aids, incontinence products (except incontinence pads), devices for compression therapy, visual aids. Additionally, contracts are used for a variety of assistive devices (e.g. hearing aids, visual aids, incontinence pads, nursing beds, orthopaedic footwear etc.). Coverage of hearing aids is restricted to specific indications only, while eligibility for visual aids is additionally subject to age specifications.

In the **United Kingdom**, while all categories seen in Table 4 are covered, coverage may be tied to certain conditions or apply only to certain device types and models. For example, to get a wheelchair funded by the NHS, a patient would need to be referred by their GP, hospital doctor, physiotherapist or occupational therapist to their local wheelchair service (waiting times can reach several weeks). While NHS wheelchairs are available to all those who have a long-term need for mobility help, more advanced ATs such as mobility scooters require private or charitable expenditure. The NHS may also loan wheelchairs to patients with short-term needs, for example following orthopaedic surgery. Perhaps similarly to the German reference pricing system mentioned above, some NHS wheelchair services offer a voucher scheme: patients receive a voucher for the value of the chair they would have received by the NHS. They can use it to cover part of the costs of a wheelchair of their choice bought privately or in partnership with the NHS (NHS 2018c). Vouchers are also available for certain types of patients (minors, those receiving income support or related allowances) to help towards the cost of glasses or contact lenses, which are typically not covered. For household aids, which are covered by the local councils upon determination of eligibility, the patient's out of pocket costs depend on the type of technology. Home equipment should be provided free by the responsible local council, as should minor home adaptations (up to GBP 1000), such as short ramps, grab rails and lighting sensors. However, more expensive home adaptations like stair rails, stair lifts and bathroom extensions usually require out-of-pocket spending. Grants for equipment and home adaptations are available from a number of charities. Hearing aids are available on the NHS as a long-term loan; the most modern options extend to behind-the-ear

(BTE) or receiver-in-the-ear (RITE) devices. More advanced models need to be purchased privately. While waiting times for getting a hearing aid on the NHS are relatively long, free batteries and repairs are covered for as long as the patient uses the device (NHS 2018d).

Table 4: Devices Included

Country \ Category	Mobility Aids	Household Aids	Respiratory Aids	Audio, Visual, Communication Aids*
Germany	X	X	X	X
Italy	X	X	X	X
Netherlands	X	X	X	X
Norway	X	X	X	X
United Kingdom	X	X	X	X

*Spectrum of category covered is variable

Purchasing arrangements and patient cost-sharing

In **Germany** assistive devices are nearly fully covered, with modest cost-sharing. Sickness funds can use three types of contracts to procure ATs: a) sickness funds and their associations are authorized to issue tenders for contracts with providers of ATs, as long as economic efficiency and quality of care are ensured (e.g. for low-cost devices such as incontinence pads); b) if no tenders are issued, the contract partners conclude contracts according to the specific details of AT care as regulated. In these cases, sickness funds have to announce publicly their intention to enter into a contract with providers (e.g. wheelchairs); c) if contracts that meet the previously described models do not exist, or if care cannot be provided in a reasonable way (e.g. in the case of customizable ATs or devices which require a high proportion of accompanying services) sickness funds and the provider of AT are permitted to conclude individual agreements on a case-by-case basis (e.g. specifically customized sitting aids). A precondition for all three types of contracts is a negotiated price which is lower than the existing reference price [(§ 127 SGB V)]. While the reference pricing system is valid for everyone with social health insurance, contracts are valid for the insured of the respective sickness funds. There are two components to the costs borne directly by users of otherwise covered AT: 1) there is a 10% coinsurance on the retail price of the AT payable to the device provider, capped at both ends (minimum of 5 and a maximum of 10 euros co-payment). For consumable ATs, patients pay a maximum of 10€ per month; 2) patients have

to cover the differential between the reimbursement limit set by the sickness funds (see previous section) and the selling price if they choose a product with a higher price than the one set in the reference pricing system or in individual contracts between their insurer and the AT provider (see above). Exemptions from co-payments in the first component are granted to specific population sub-groups (e.g. children up to the age of 18 years, low-income or high-need patients) and there is a cap of total out-of-pocket expenditure set at 1% of annual income.

In **Italy**, the Ministry of Health establishes the categories of assistive devices eligible for provision through the NHS as well as their prices, detailed in the Tariff Catalogue (see above). ATs included in the tariff catalogue are supplied free of charge or reimbursed up to the levels stipulated in the list (users opting to purchase more expensive products have to cover the difference between reference and product price, as in Germany, above). For the ATs in List n. 1 (e.g. audio, visual and communication aids) and 3 (e.g. respiratory aids) of the Tariff Catalogue, reimbursement prices are set centrally and the local health authorities procure them from the manufacturing companies. For the ATs in List n. 2 (including mobility and household aids), local health authorities procure them through tenders. In general, users are free to choose their AT suppliers they wish, unless there is a public procurement contract with specific companies. Repairs of devices under warranty are provided by the manufacturing company supplying the local health authority; it is the responsibility of the patient to contact the company (or the supplier of ATs in List 2). The Tariff Catalogue indicates which repairs are to be borne by local health authorities in all other cases (outside warranty).

In **the Netherlands**, some cost-sharing applies, e.g. 25% on hearing aids or 69 euro for orthopedic shoes. Also, ATs count towards the general deductible of 385 euro applicable for all services used under the ZVW. Children below 18 are exempted. For ATs under the WMO mostly income-dependent cost-sharing applies and varies strongly among municipalities. Only wheelchairs are currently excluded from cost-sharing by law. However, there is a plan to introduce a fixed co-pay of 17.50 euro per month for all ATs via the Wmo in 2019. Under the Wlz, there is generally no cost sharing requirement. Many Dutch citizens also purchase supplemental insurance to cover AT costs. Under the Zvw, there are hardly any devices for which cost-sharing applies (beyond the ones mentioned above, artificial hair for cancer patients has a co-pay); the supplemental insurance may cover non-covered ATs, such as glasses, or part of the cost-sharing (e.g. for hearing aids). No supplemental insurance exists for ATs delivered via the Wmo. In a recent survey, 38%

of AT users experience OOP as problematic. Before purchasing a device, 31% of respondents did not know whether it would be reimbursed and 21% were uncertain about whether cost-sharing would apply. Therefore, there seems to be room for improvement regarding both the availability of Information as well as patients' awareness of its existence. Regarding contracting arrangements, the same survey showed that 32% of Dutch AT users lament that they can only receive products from manufacturers that have a contract with their insurer or municipality and 30% complain that choice is too limited (28% see limited choice as a real problem) (Van Harten & Toersen 2015). It should be noted that de facto choice may be higher than the respondents realize; it is possible that the insurer or municipality direct consumers to certain devices as a result of selective contracting or used guidelines even though they are entitled to different devices as well.

In Norway, most ATs are provided to users free of charge. Financial support is not given for ATs which are routinely used by non-disabled persons. These can be household appliances such as washing machines, television sets and ordinary kitchen equipment. However, extra equipment to adapt these appliances would be covered in the AT system. Similarly, for car-related adaptations, the provision of the vehicles themselves is subject to income restrictions but the equipment for adapting them to the user's needs is covered. For major categories of ATs, the Norwegian Labour and Welfare Service enters into procurement framework agreements for the whole country with individual dealers. These ATs constitute the national assortment. Assistive technology centres make their own agreements directly with the dealers for some of the smaller categories of ATs. The national assortment covered 90-95% of all ATs dispensed in 2016 (NAV 2017). There is a well-functioning system on refurbishment of used ATs. The devices are cleaned and maintained before they are provided to new users. Refurbished assistive devices represented a new price value of approximately 78 million euros in 2016. In the same year, around 29% of the assistive devices provided to users were refurbished ones. The Norwegian government appointed an expert commission in 2015-2016 to carry out a comprehensive evaluation of the Norwegian policies on assistive devices, examining organisational principles, cost-effectiveness and the level of competence in provision as well as predict future demands. In 2017, following their evaluation, the commission recommended continuing with current practice for investment in crucial assistive technologies, as defined by the National Insurance Act. The ongoing nationwide municipal reform, reducing the overall number of municipalities from 422 to 356 by 2020, aims to strengthen and

achieve better integration of local social welfare and healthcare services. Accordingly, the commission report suggests shifting responsibility for the procurement of more basic and highly frequent assistive technologies from the state to the municipalities (Government of Norway 2017).

In the **United Kingdom**, ATs made available by the NHS are generally free of charge and provided directly in the context of service delivery. For certain types of ATs, such as wheelchairs, a voucher scheme is in place, enabling broader choice for users, who can obtain their devices from certain retailers and cover any expenses exceeding the value of the voucher they have been issued (see more detail under “Devices included”, above). Relevant to the taxonomy used for this work, AT for mobility aids, hearing and vision aids (excluding, as in other countries in this work, regular prescription eye glasses and contact lenses) and communication aids, as well as orthoses and prostheses are generally provided free of charge under the NHS. In June 2006 the Department of Health launched an initiative to transform the way community equipment, such as ATs, was provided. The new approach was based on a principle similar to that of the voucher scheme as well as to processes like the ones in other countries, like Germany, aiming to enhance patients’ choice and control. This initiative, named “Transforming Community Equipment Services” introduced the so-called “Retail Model” of AT provision, also known as the “National Catalogue Prescription Scheme”, which is in operation in some parts of the country (local authorities could decide on participation). For devices falling under the category of “Simple Aids to Daily Living (SADLs)”, relevant health professionals issue a prescription that can be filled at accredited retailers. This means that users can choose both the retailer and the specific item of equipment they wish to own as well as “top up” and opt for more expensive models than the ones they would have been issued by integrated services, covering the cost difference out of pocket. A national catalogue of equipment that may be provided by prescription has been developed, including tariff prices, with flexibility on which of the items in the catalogue will be included in schemes at local level. For example, some models of grab rails, raised toilet seats and a small range of sensory communication equipment are included in the national catalogue (DLF 2018). Even in areas operating the scheme, more complex equipment with high maintenance needs is still provided by the public services in the traditional way and is essentially “loaned” to the user, as are customized ATs (such as hearing aids).

Table 4: Coverage

Country	Category	Full Coverage?	Partial Coverage?	Government payer of last resort?	Loaned Devices? (deposit, rental fee)	Tax Deductions?
Germany		yes	yes	no	some	no
Italy		yes	yes	no	some	yes
Netherlands		yes	yes	no	some	yes
Norway		yes		no	yes	no
United Kingdom		yes	yes	no	yes	no

Evidence-based decision-making for coverage of ATs

In European countries, it is common practice to carry out post-marketing evaluations of the consequences on introducing a (new) technology in the statutory health system, known as **health technology assessment (HTA)**. HTA aims to enable evidence-based coverage decision and aid reimbursement and/or pricing processes, depending on the system. Beyond safety and clinical effectiveness, HTA often deals with the economic, social, ethical, legal and organizational implications of a health technology. Formal evaluation tracks linked to coverage decision-making are almost universally in place for pharmaceuticals, but an increasing number of countries also evaluates medical devices to determine the conditions of their financing from public funds. However, ATs are not as frequently evaluated as other technologies.

Indeed, the remit of the majority of European HTA institutions mainly encompasses the assessment of high-risk medical devices or those with a high economic impact. An overview of institutional capacity and process in most of the countries in our sample can be found in Annex 1. Medical aids used directly by patients seem to be less frequently considered, usually due to the regulatory background. Recent work from our Department mapped HTA reports produced by European HTA institutions between 2005 and 2015 on a taxonomy for medical devices which assigns separate positions to device types depending on functionality, risk level and diagnostic or therapeutic purpose. We found that out of a sample of 1237 reports on medical devices, produced by 33 institutions, only 7% (n= 86) evaluated assistive devices (a detailed breakdown and relevant sources are provided in Annexes 2 and 3).

Outlook

All countries in the sample examined above seem to provide comprehensive coverage to the ATs examined in this work, although some systems (e.g. Norway), seem to be easier to navigate than others (e.g. the Netherlands). The regulatory framework and level of delivery of ATs and related services mirror the general structure of the system, but intersectorality is an important issue that needs further exploration before the breadth and meaningfulness of access to ATs for the population can be truly evaluated. This was also recognized by the European Parliament, whose European Technology Assessment Group carried out a comprehensive evaluation of the provision, utilization and future perspectives of ATs in Europe. In the overview of the study's key results, it is clearly stated that "(...) a proactive approach should be taken to ensure that current and future ATs respond to the needs and challenges of society. (...) A 'one size fits all' approach to promoting ATs may be inappropriate, as individuals have different needs, desires and preferences, and live in different social, economic and infrastructural contexts. (...) Technology alone is not enough and should be combined with social and regulatory action." (EPRS 2018).

Even in countries with National Health Service systems, some flexibility seems to be granted to the local level regarding both coverage and procurement options, which mirrors practices in insurance systems. Research from Germany shows substantial regional variations in the utilization of ATs, which may be not solely attributable to morbidity gradients; no explanatory work seems to have been carried out yet, but variability in practices of individual insurers and prescribers could be a contributing factor, mirroring evidence from other countries with flexibility at the point of service delivery (e.g. the Netherlands). Evidence from the Netherlands suggests AT users may face challenges in choice limitations and OOP resulting from contracting practices and benefit design, respectively. Choice limitations seem to have been an issue in the UK, motivating changes that led to the introduction of a "retail model" of AT provision, which has, however, not been uniformly adopted across the country. However, a more granular look is required to better understand the dynamic of contracting arrangements and their impact on availability and financial protection. This presupposes the availability of good data across the studied countries; a first attempt by collaborators in this report to identify corresponding datasets suggests that only a limited set of questions would be easily explored and that there is variability within the sample in the scope and quality of available information.

Information availability is an issue in a different respect as well: overall, countries differed in the amount, level of detail and presentation of online information regarding the reimbursement of ATs and/or ways of obtaining them. While the English NHS provided detailed information on most of

the AT categories included in this work in its NHS Choices pages, research from the Netherlands suggests that in the area of ATs, the vast majority of users look for personal advice, especially that of their provider, rather than guidance from online sources (Van Harten & Toersen 2015).

While charities related to the provision of services, including ATs, for persons with disabilities seem to be active in all countries in the sample, the most formalized role appears to be in the UK. The aforementioned NHS Choices website clearly points users in the direction of charity support (for two examples, see Annex 4).

Previous work suggests that evidence-based approaches are not the norm for the inclusion of (new) assistive devices in positive lists among the studied countries. The necessity for such evaluations is not self-evident and a more detailed analysis of their meaningfulness in this context could be indicated. In general, a more in-depth look at individual aspects from this work, potentially backed by quantitative analyses would be welcomed by the authors.

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ANNEXES

Annex 1 - Overview of selected institutions and information about their role and scope (HTA of MDs in European Countries)

Supplementary material: From Fuchs S, Olberg B, Panteli D, Busse R (2016): Health Technology Assessment of medical devices in Europe: processes, methods and practices. *Int J Technol Assess Health Care*; 32(4):1-10. DOI:10.1017/S0266462316000349

Country	Institution	Role		Scope				
		Type of institution	Date of establishment	Types of technologies addressed	Evolutionary stage technologies assessed	Explicit process for priority setting	Criteria for priority setting	Definition of Medical devices
DE	DAHTA@DIMDI*	National governmental institution	2000	D, MD, P, S	ES, N	Yes ^b	2-5, 6	Regarding EU law (93/42/EEC, 90/385/EEC, 98/79/EC)
	G-BA	National governmental institution	2004	D, MD, P, S	ES, N	<i>Not applicable (depends on the pathway, mostly requests by stakeholder organisations)</i>		Regarding EU law (93/42/EEC, 90/385/EEC, 98/79/EC) and institutions own definition
	IQWiG	Independent research entity with function as governmental institution	2004	D, MD, P, S	ES, N	<i>Not applicable (set by commissioning institution: G-BA, MoH; criteria only for patient documents in place)</i>		Definition of technology/ health technology (including MDs)
IT	Agenas	National governmental institution	1993	MD, P	ES, N, E	<i>Not applicable (set by commissioning institution: RHS, NHS)</i>		Regarding EU law (93/42/EEC, 90/385/EEC, 98/79/EC)

Country	Institution	Role		Scope				
		Type of institution	Date of establishment	Types of technologies addressed	Evolutionary stage technologies assessed	Explicit process for priority setting	Criteria for priority setting	Definition of Medical devices
	ASSR	Regional governmental institution	1995	MD, P	E	No information		No information
	Regione Veneto	Regional governmental institution	1993	D, MD	E	No information		No information
	A. Gemelli UVT	Hospital unit/group	2001	D, MD, P, S	No information	No		No information
	ZiN	Independent research entity with function as governmental institution	1949	D, MD, P, S	ES, N	Yes	2-5	No information
NL	iMTA/iBMG	Independent research entity (non-academic)	1988	D, MD, S	No information	No information		No information
	NOKC	Independent research entity with function as governmental institution	2004	D, MD, P, S	ES, N, E	Yes	2-4, 6	No information
UK/ Eng- land & Wales	BAZIAN	Company	1999	D, MD, P	No information	No information		No information
	CRD	Independent research entity (academic)	1994	D, MD, P, S	ES, N	Not applicable (set by commissioning institution)		Definition of technology/ health technology (including MDs)

Country	Institution	Role		Scope				
		Type of institution	Date of establishment	Types of technologies addressed	Evolutionary stage technologies assessed	Explicit process for priority setting	Criteria for priority setting	Definition of Medical devices
	NICE	Non-departmental public body with legislative function	1999	D, MD, P, S	ES, N	Yes	1-4 ^e	Regarding EU law (93/42/EEC, 90/385/EEC, 98/79/EC)
	NIHR_HSC	Independent research entity with function as governmental institution	1998	D, MD, P, S	E	Yes	6	No information
	NIHR_NETSCC	Independent research entity with function as governmental institution	1996	D, MD, P, S	ES, N	Yes	2-4, 6	Definition of technology/health technology (including MDs)
	PenTag	Independent research entity (academic)	No information	D, MD, P	ES, N	Not applicable (set by commissioning institution)		Not applicable (defined by commissioning institution)
	Unif Shef	Independent research entity (academic)	2002	D, MD, P	ES, N	Not applicable (set by commissioning institution)		Not applicable (defined by commissioning institution)
UK/Scotland	SHTG/HIS	National governmental institution	2011	D, MD, P, S	ES, N, E	Yes	2-6	Definition of technology/health technology (including INHATA/HTAi definition from HTA glossary)

Notes: D= Drugs, MD= Medical Devices, P= Procedures, S= Systems; Evolutionary stage of technologies assessed (own categorisation): ES= Established, N= New, E= Emerging; Criteria for selection and prioritisation of technologies for assessment: 1. Societal criteria, 2. Economic criteria, 3. Epidemiological significance of disease/burden of disease, 4. Medical-scientific criteria, 5. Criteria concerning HTA production (e.g. feasibility), 6. Other criteria that don't fit in the categories (e.g. criteria depend on commissioning institution; within the scope of the mission); Definition of Medical Devices: own categorization based on available information; ^a reviews only technologies which have been 'contested or are controversial' as to their effectiveness, appropriateness, and/or cost-effectiveness; ^b via Delphi approach; ^c HTA has also been used to assess medical technology and services, though only informally; ^d on a trial basis; ^e refers to the technology appraisal process, criteria in place for the different tracks; * no further research grants for HTA projects beyond 2015.

Annex 2 - Taxonomy for medical devices and number of technologies identified during the plausibility testing including actual examples from the HTA report pool

From Fuchs S, Olberg B, Perleth M, Busse R, Panteli D (2018): Testing a new taxonomic model for the assessment of medical devices: is it plausible and applicable? Insights from HTA reports and interviews with HTA institutions in Europe. Health Policy; Available online 14 March 2018; <https://doi.org/10.1016/j.healthpol.2018.03.004>

Classification criteria of EU-Directives according to risk aspects:		Classification according to the relevance of product & service and reimbursement characteristics (includes OECD Classification of Health Care Functions) + HTA logic											
		Diagnostic Technologies 409						Therapeutic Technologies 987					
		Assistive technology devices (directly used by patients) A1		Artificial body parts (implanted by medical procedure) B1		Medical devices for the assistance of medical professional C1		Assistive technology devices (directly used by patients) A2		Artificial body parts (implanted by medical procedure) B2		Medical devices for the assistance of medical professional C2	
		Example	No.	Example	No.	Example	No.	Example	No.	Example	No.	Example	No.
93/42/EEC	I		0			Ophthalmoscope	9	Wrist splint; Insoles	27			Wound dressing	11
	Ila	Home blood pressure monitor	13			MRI; Ultrasound	177	Hearing aids	18	Grommets; Dentures	12	TENS device	128
	Ilb					X-ray imager	79	Insulin pumps	17	Intraocular lenses; BAHAs	91	Endovenous laser therapy	341
	III			Pulmonary artery pressure monitor	1	OCT using catheter	1	Silver dressings	4	Stents; TAVI	126	Intracoronary brachytherapy	128
90/385/EEC	IV			ICD: heart monitor unit	7					ICD: defibrillator unit	84		
98/79/EC	V	Glucose strip; Pregnancy test	7			HPV test; Genetic tests	115						

Annex 3 – Examples of HTA reports on ATs

Mobility aids

- ❖ CAHIAQ (Aguas): Ortesi de genoll postreconstrucció del lligament creuat anterior (Using a knee brace after reconstruction of the anterior cruciate ligament), 2011: http://aquas.gen-cat.cat/ca/detall/article/ortesi_genoll_postreconstruccio_LCA_IN_aiaqs2011ca
- ❖ NICE: The geko device for reducing the risk of venous thromboembolism (MTG19), 2014: <https://www.nice.org.uk/Guidance/MTG19/resources>
- ❖ NIHR: Graduated compression stockings for the prevention of deep vein thrombosis in post-operative surgical patients; a systematic review and economic model with a value of information analysis, 2015: <https://www.journalslibrary.nihr.ac.uk/hta/hta19980#/hometab0>
- ❖ SHTG/HIS: Advice Statement 006/13 Are wrist splints or steroid injections clinically and cost-effective in mild to moderate carpal tunnel syndrome compared with decompression surgery?/ Technology Scoping Report 15 Can wrist splints or steroid injections reduce the need for decompression surgery in carpal tunnel syndrome: http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/earlier_advice_statements/advice_statement_006-13.aspx

Household aids

- ❖ HAS, 2010: above

Respiratory aids

- ❖ FinOHTA: Mechanical non-invasive cough assist device, 2010: https://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi1ve2gJHaAhVEKIAKHVBKDnoQFggsMAA&url=https%3A%2F%2Fthl.fi%2Fattachments%2Fhalo%2Fsummaries%2FSLL_2010_Mekaaninen_yskit-yslaite_yskimisen_avustamisessa_eng.pdf&usq=AOvVaw1lzKCN_xamPbxJKXUzbJjh
- ❖ HAS: Evaluation des dispositifs médicaux et prestations associées pour la ventilation mécanique à domicile (mechanical ventilation, home), 2013: https://www.has-sante.fr/portail/jcms/c_1348270/fr/evaluation-des-dispositifs-medicaux-et-prestations-associees-pour-la-ventilation-mecanique-a-domicile

- ❖ KCE: Home Oxygen Therapy, 2008: https://kce.fgov.be/sites/default/files/at-oms/.../kce_156c_home_oxygen_therapy_0.pdf
- ❖ NICE, UK: Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (TA139), 2008 (Update in 2012): <https://www.nice.org.uk/guidance/ta139>
- SHTG/HIS: Airsonett® (temperature controlled laminar airflow device), 2015: http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_imto/imto_003-2015.aspx

Audio, Visual, and communication aids

- ❖ HAS: Devices for hearing impairment (Evaluation des appareils électroniques correcteurs de surdité), 2008: https://www.has-sante.fr/portail/jcms/c_702730/fr/evaluation-des-appareils-electroniques-correcteurs-de-surdite
- ❖ KCE: Hearing aids in Belgium: health technology assessment, 2008: <https://kce.fgov.be/en/hearing-aids-in-belgium-health-technology-assessment>

Annex 4: Examples from the NHS Choices Website

Example 1: [Mobility aids](#)

How to get an NHS wheelchair or scooter

NHS wheelchairs are available to people of all ages who have a long-term need for mobility help. However, your eligibility will be decided locally and can vary depending on where you live.

Some wheelchair services or local hospitals will also provide wheelchairs on loan in certain circumstances – for example, following surgery.

The NHS is unlikely to provide you with a mobility scooter.

NHS wheelchair services

Before you can get a wheelchair on the NHS, you'll have to have an assessment. This is done by the NHS wheelchair service, and will decide whether you're eligible for an NHS wheelchair and, if so, what type.

Assessments are usually carried out at the wheelchair service centre. You can have the assessment at home or at work, but you won't be able to see and try the full range of chairs available.

To get an NHS wheelchair assessment, ask your GP, hospital doctor, physiotherapist or occupational therapist to refer you to your [local wheelchair service](#). Many wheelchair services have a waiting list for assessments, so expect it to take several weeks after being referred.

How to [access a local physiotherapist](#).

How to [get occupational therapy](#).

NHS voucher scheme

Some NHS wheelchair services offer a voucher scheme to widen your choice of wheelchair.

You receive a voucher for the value of the chair you would have been offered after your assessment that you can put towards the cost of a chair bought privately or in partnership with the NHS.

Other ways to get a wheelchair or scooter

Motability hire schemes

The [Motability Scheme](#) can be very useful if you want to hire or buy an electric wheelchair or scooter.

It's a not-for-profit scheme that allows people who receive the high-rate mobility component of [Disability Living Allowance](#) or the [War Pensioners' Mobility Supplement](#) to use their benefits to hire or hire purchase an electric wheelchair or scooter.

Local authority wheelchairs

Local authorities provide wheelchairs as part of their duty to help disabled children access education.

As well as providing children with wheelchairs, local authorities are responsible for carrying out home adaptations if you need to use a wheelchair at home.

The local authority is unlikely to provide you with a mobility scooter.

Contact your [local authority](#) for more information about what's available for you.

Charity wheelchairs

Local Red Cross branches can often [lend wheelchairs and equipment](#) for short periods.

Some towns or shopping centres have a [Shopmobility scheme](#), where you can borrow a wheelchair or scooter to go shopping. It's run by volunteers and is usually free.

Better Mobility has a [list of charities that can help to fund mobility equipment](#).

Example 2: [Home equipment](#)

Home equipment: what's free and what's not

What's free

If a care needs assessment has concluded that you need this equipment, it should be provided free by your local council.

Minor home adaptations costing less than £1,000 are also free from your local council. These are often related to mobility and falls prevention, such as:

- a short concrete ramp or shallow steps
- grab rails
- automatic lighting at your front door

What you have to pay for

You may have to buy very small household aids yourself, such as kettle tippers. Use the self-assessment website, [AskSARA](#) to find out about the sort of equipment that is available and details of suppliers.

Councils can charge for larger, more expensive home adaptations. These include:

- stair rails
- ramps
- stairlifts (around £2,000 - £7,000)
- bathroom extensions

[Apply for equipment at home if you're disabled](#)

Grants for equipment, aids and home adaptations

Some home adaptations are expensive, but it may be possible to get help with the costs.

- a [Disabled Facilities Grant](#) is available for home adaptations
- the charity [Independence at Home](#) has grants for disabled people and those with a long-term illness
- Some local authorities can help with urgent home alterations or improvements

Where to find more help

Before you're provided with equipment or you buy it, it's worth getting independent advice to make sure it'll best meet your needs:

- [Rica](#) is an independent organisation that carries out consumer research for older and disabled people
- [Disabled Living Foundation \(DLF\)](#) is a national charity that provides free, impartial advice about all types of home adaptation and mobility products for disabled adults and children, older people, and their carers and families.
- [Independent Age](#) has advice on home adaptations
- Which? Elderly Care has information on [stairlifts](#) and [choosing and fitting grab rails](#)
- The Money Advice Service has advice about [shopping around for disability aids and equipment](#)

The North American Observatory on Health Systems and Policies (NAO) is a collaborative partnership of interested researchers, health organizations, and governments promoting evidence-informed health system policy decision-making. Due to the high degree of health system decentralization in the United States and Canada, the NAO is committed to focusing attention on comparing health systems and policies at the provincial and state level in federations.

