EVIDENCE REPORT

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Converge3

Integrating health, economic and equity evidence to inform policy

Assistive Devices Coverage: Ontario Compared to Other High-Income Jurisdictions

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North American Observatory on Health Systems and Policies

About this Report
Converge3 commissioned the North American Observatory on Health Systems and Policies (NAO) to conduct reviews of regulation and coverage of assistive devices in Canada and a selection of other high-income countries. The NAO gratefully acknowledges the support of their colleagues from the Berlin University of Technology, the University of Auckland's Health Systems, School of Population Health, and the Australian Institute of Health Innovation. In addition to a drawing on findings from four separate reports on regulation and coverage of assistive devices in eight high-income countries (published as a consolidated report by Converge3), this comparison report draws on questionnaire data collected for the same jurisdictions. Converge3 receives funding from the Province of Ontario. The views expressed in this report are those of the authors and do not necessarily reflect those of Converge3 or the Province of Ontario.

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About 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 Province of Ontario and includes multiple partner organizations, including Li Ka Shing Knowledge Institute at St. Michael's Hospital, McMaster University, Ottawa Hospital Research Institute, ICES, Health Quality Ontario, Public Health Ontario, and the Ministry of Health and Long-Term Care.

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Introduction

This study compares Ontario to other high-income jurisdictions within Canada, and outside Canada in Western Europe and Australasia, in terms of coverage for assistive devices, also known as assistive technologies. Since assistive devices are not included as "insured services" under the Canada Health Act, and are therefore not part of universal health coverage in Canada, coverage decisions for assistive devices are made at the provincial level in Canada. Therefore, the following description of Ontario's coverage policies for assistive devices is put within the context of other provinces as well as countries where national authorities are mainly responsible for coverage policies on assistive technologies.

In addition to individual reports on the 13 provinces and territories within Canada (Peckham, Kashef Al-Ghetaa, Ho, & Marchildon, 2018), five countries within Europe (Panteli & van Ginneken, 2018), Australia (Braithwaite, Westbrook, Nguyen, Warwick, & Boyling, 2018) and New Zealand (Shekhawat, Wilkinson-Meyers, & Tenbensel, 2018), we have based this report on a common templated questionnaire prepared for Ontario, Germany, Italy, the Netherlands, Norway, the United Kingdom (England), Australia and New Zealand. The completed template questionnaires have been appended to this report.

For the purposes of this review, the North American Observatory on Health Systems and Policies (NAO) and its collaborators in Europe, Australia and New Zealand have adopted the following definition for assistive devices from the Assistive Technology Act 2004 in the United States: "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" (Congress United States of America Government, 2004). Ontario's approach to the coverage of assistive devices has been shaped by two different policy regimes–disability policy and health policy. The impetus behind these regimes differ. Disability policy has been largely driven by human rights laws and initiatives which have extended the rights of the physically disabled throughout the world since the Second World War (Iriarte, McConkey, & Gilligan, 2016). Assistive devices and technologies are tools designed to support individuals in the management of their day-to-day life (Prince, 2011; Baños, 2016; MacLachlan, Mannan & McVeigh, 2016; Mattison, Wilson, Wang, & Waddell, 2017).

The more general programs, services, and subsidies to facilitate access to assistive devices by disabled persons extend well beyond health and healthcare and can be within the responsibility of any government department or agency. However, to the extent that some of these services considered "health needs" as defined by national and subnational ministries of health, they fall within the purview of publicly financed health programs and services under the stewardship of a health ministry or delegated agencies. Given the two different policy regimes, Ontario is not unique in having more than one program spout for assistive devices.

Ontario: Two Main Programs for Assistive Devices

The Ontario Disability Support Program Act, 1997, is the legislative framework for income supports for disabled persons. As a social determinant of health, income plays a key role in determining the health outcomes of persons living with disabilities. However, this law and associated income supports for disabled persons do not directly address access to assistive devices.

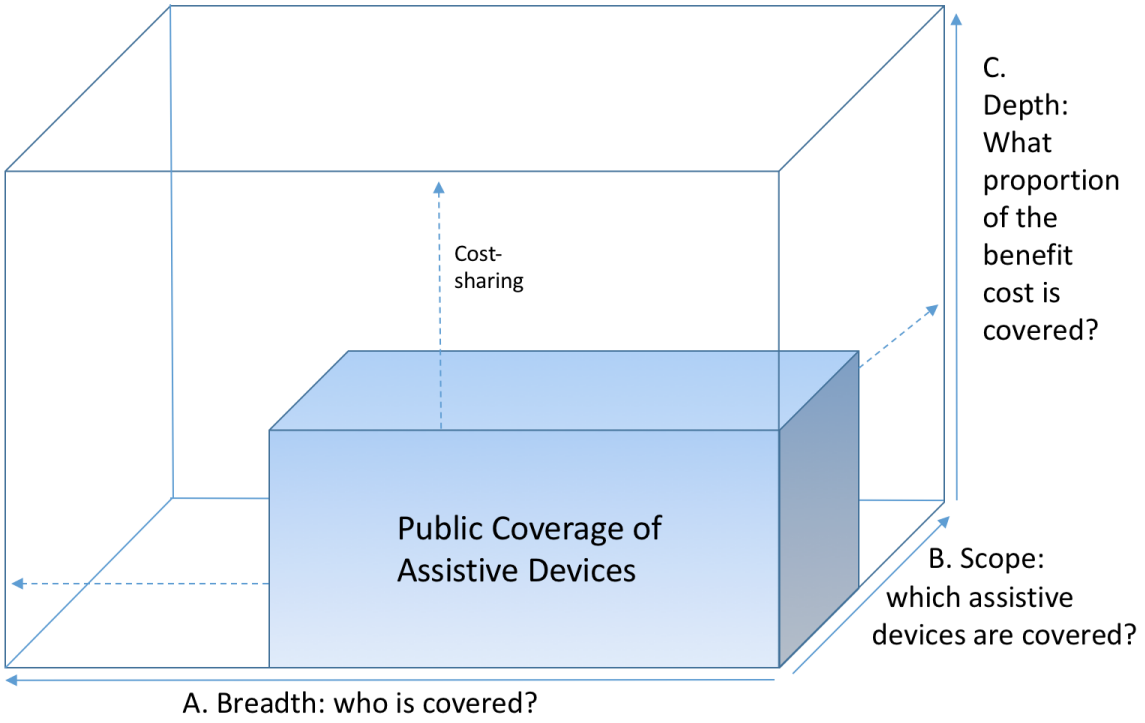
Instead, there are two main programs for assistive devices in Ontario: 1) the Ontario Disability Support Program (ODSP) administered by the Ministry of Community and Social Services (Government of Ontario, 2005); and 2) the Assistive Devices Program (ADP) administered by the Ministry of Health and Long-Term Care (Government of Ontario, 2016).

The ODSP provides income and employment supports to persons living with disabilities. Any individual receiving ODSP support is automatically eligible for the Assistive Devices Program. In general, the ADP will pay up to 75 percent of the cost of approved devices and the ODSP program can help supplement the costs. Since the purpose of this report was to focus on publicly administered assistive devices programs this analysis focuses nearly exclusively on ADP except where ODSP fills in the gaps left by ADP, including covering some of the out-of-pocket costs for assistive devices.

Coverage Decisions

Drawing upon the World Health Organization's (2010) coverage cube for universal health coverage, that was also used in the report on assistive technologies in five European countries (Panteli & van Ginnekan, 2018), Figure 1 illustrates the three dimensions of coverage for assistive devices: the breadth of coverage with respect to determining eligibility; the scope of coverage in terms of the number and type of assistive devices; and the depth of coverage in terms of what is left for individuals to pay, with or without the contributions of private charities and non-governmental organizations.

Figure 1: Three Dimensions for Coverage for Assistive Devices



Source: The authors' adaptation of the WHO (2010) framework for universal health coverage.

A. Breadth: Who is Covered

To be considered for assistive devices coverage under the Ministry of Health and Long-Term Care's Assistive Devices Program, an applicant must have a valid Ontario health card which, in turn, requires a minimum of three months residency in the province. In addition, the applicant must be assessed by a physician or qualified professional who is registered with the ADP and have a longer-term physical disability, defined as a disability that has lasted a minimum of six months (Peckham et al., 2018). The physical disability must be of a nature that the assistive device required cannot be required exclusively for sports, work or school. In other words, the assistive device must be to support the everyday health and social needs of the applicant.

Similar to Ontario, eligibility in Italy, Germany, Norway, Netherlands, England, Australia and New Zealand, is determined by an assessment from a health professional (Braithwaite et al., 2018; Panteli & van Ginneken, 2018; Peckham et al., 2018; Shekhawat et al., 2018). All jurisdictions other than Australia make specific mention that the assessor is either registered with the program or is connected to the government authority providing the program (e.g., in Norway the assessor is often an occupational therapist from the local authority). These assessments are then followed up with a prescription by the health professional that identifies the device or supplies (that are covered) to support the needs of the individual (Braithwaite et al., 2018; Panteli & van Ginneken, 2018; Peckham et al., 2018; Shekhawat et al., 2018).

Like Ontario, New Zealand and the Netherlands also requires a disability of a minimum duration of six months in order for an individual to be considered eligible (Shekhawat et al., 2018). In the Netherlands, those who require support for less than six months fall under the Health Insurance Act while longer-term use under the Social Care Act (Panteli & van Ginneken, 2018). Norway goes much further in requiring a more permanent disability – in excess of two years (Panteli & van Ginneken, 2018). Disabled Norwegians requiring short-term support are expected to apply for financial support elsewhere (usually through the local authorities).

In Germany, individuals receiving social health insurance are eligible for assistive devices similar to ODSP-eligible residents of Ontario. However, only in England (among the countries canvassed here) is income used as a major eligibility criterion (Panteli & van Ginneken, 2018).

In Ontario's ADP, there are also carveouts from this eligible population. The program will not pay for disables persons who are able to get assistive devices under the Workplace Safety and Insurance Board (workers' compensation). Eligible Armed Forces veterans as defined in the *Veterans Health Care Regulations* under the authority of the *Department of Veterans Affairs Act* cannot apply for coverage under the ADP. Both of these exclusions are common to most extended health benefit plans administered by provincial and territorial departments/ministries of health in Canada and are in place mainly to prevent double coverage or double payment of benefits by public authorities. There are also similar carveouts for the same reasons in the high-income countries that were examined as part of this project.

B. Scope: Which Assistive Devices are Covered?

We selected four categories of assistive devices where the cost of purchasing is high to compare coverage across jurisdictions: the first is mobility aids and includes devices such as wheel chairs, walkers and crutches, with certain types of powered wheel chairs being among the more expensive equipment. Household aids were the second category and included assisted devices such as hospital beds, stair lifts, transfer lifts and various bathroom devices. The third category were respiratory aids including continuous positive airway pressure (CPAP) machines and oxygen support. The fourth and final category were audio, visual and communication aids including bone-anchored hearing aids as well as less expensive adaptive telephones and reading or writing devices.

All the devices in the four above-mentioned categories were included in Ontario's ADP (Peckham et al., 2018). The breadth of coverage is greater in Ontario than that offered by governments in Australia and New Zealand (Braithwaite et al., 2018; Shekhawat et al., 2018). For example, visual aids in Australia are not covered publicly. In addition, coverage for respiratory aids in both Australia and New Zealand are more variable than in Ontario.

Ontario's coverage compares relatively generously to the Western European countries examined here. In Germany, for example, hearing aids are restricted to specific conditions. Within Europe Norway appears to have the broadest coverage, where coverage can not be denied and devices used for sport are also covered. Italy, offers a similarly broad range of devices however, communication devises and those used for learning and cognitive development are not covered to the same extent. Recent changes to the Dutch insurance system has removed certain assistive devices categories (walkers, crutches, special chairs) from coverage in the Netherlands. Both England and Germany offer a voucher system where individuals receive a voucher for the value of the device they would have received through the government program that can be used to cover the cost of a device of their choice. In England this voucher system is also used towards the cost of visual aids (Panteli & van Ginneken, 2018).

The ADP also covers the cost of replacing mobility aids and respiratory aids as a result of changes in quality or medical condition (Government of Ontario, 2016). Public regimes, including Ontario's ADP, should consider the rapidly changing nature of assistive devices, a product of a fast changing and innovative environment. This involves both improvements in terms of the functionality, quality and safety of existing products and the wholesale replacement of older devices with entirely new devices. In terms of the latter, the ADP may consider listing a new device.

Assistive devices can also be removed from the list of eligible equipment under the ADP if the device is no longer considered safe, reliable, or cost-effective. An assistive device can also be removed from the ADP list if the device is no longer being supported by the manufacturer or distributor or the manufacturer or distributor are no longer abiding by the policies and procedures of the ADP. Finally, a device can be removed if it is no longer being used by program recipients.

Of course, only assistive devices which are currently available on the Canadian market can be considered for this list in the ADP manual. The regulatory system for market approval of all medical devices, including assistive devices, is determined at the federal level of government, by Health Canada.

C. Depth: What Proportion of the Benefit Cost is Covered?

As is the case in other provincial and territorial jurisdictions as well as the selected high-income countries examined as part of this project, governments and delegated public authorities generally do not cover the full cost of assistive devices. Some cost-sharing is generally expected. In the case of Ontario, the ADP pays up to 75 percent of the total cost of assistive devices on the approved ADP list. This leaves disabled persons with a minimum of 25 percent of the cost (Peckham et al., 2018).

In England, Norway, New Zealand, and Italy most assistive devices are made available free of charge (Panteli & van Ginneken, 2018; Shekhawat et al., 2018). The Netherlands, Australia, and Germany, like

Ontario, have some form of cost-sharing for assistive devices (Braithwaite et al., 2018; Peckham et al., 2018; Shekhawat et al., 2018). Although, as noted above, England offers a voucher system for certain types of assistive devices (e.g., wheelchairs). This voucher scheme allows for greater choice for individuals. In particular, they are at liberty to purchase more expensive equipment than the public subsidy allotment as long as they are willing to pay for any amount in excess of the value of the voucher (Panteli & van Ginneken, 2018).

It should be noted that the Ontario Disability Support Program (ODSP) can assist with some of the costs not covered by the ADP. These costs include the consumer contribution for an assistive device under the ADP program and an assessment fee that is required to be approved for the ADP (Government of Ontario, 2018).

In addition, some charitable and non-governmental organizations can provide supplemental supports to administer government programs as well as support the costs to individuals. Ontario relies on several organizations (e.g., Easter Seals Ontario, March of Dimes Ontario, War Amps, Kiwanis, and Lions Clubs) to assist individuals in any additional out-of-pocket costs (Peckham et al., 2018). In England individuals can apply for grants from a number of charities to support the cost of equipment and home modifications (Panteli & van Ginnekan, 2018). Western Australia has a high involvement of charitable organizations where state funding is outsourced to Disability Sector Organisation Providers and while these organizations do not manage the funding they are heavily involved in consultation activities (Braithwaite et al., 2018). This arrangement is similar to that which has been established in New Brunswick (Peckham et al., 2018). New Zealand does not have a strong tradition of well-resourced and independent philanthropy and as such was only able to identify one organization (Workbridge) that seemed to allocate funding for those who were not eligible for Ministry of Health funding for assistive devices (Shekhawat et al., 2018)..

Conclusion

As discussed in the introduction, the impetus for government intervention in subsidizing assistive devices for the disabled comes from two distinct sources, the disability rights movement and the expansion of health coverage by the state. In Ontario, this has resulted in an income support regime for the disabled in addition to various rights (e.g. access in public buildings) as well as general disability support programs. Publicly funded coverage for assistive devices is largely managed through the Ministry of Health and Long-Term Care's Assisted Device Program. It appears, however, that the more general program, the ODSP, is designed in a way to supplement the ADP.

Ontario is no different than other jurisdictions in being careful in its definition of disability for cost containment. In all cases, a professional assessment of disability is required. In requiring that the individual suffers from a longer-lasting disability (minimum 6 months), Ontario is no different than New Zealand and the Netherlands, a period that is considerably shorter than the two years required in Norway.

Based on the four higher-cost categories of assistive devices examined here, Ontario has at least as broad, if not broader, scope of coverage than most jurisdictions. With the exception of Norway which appears to have one of the broadest coverage regimes in the world for assistive devices. In addition, the ADP list of assistive devices appears to be designed to adjust rapid technological change by removing older devices and adding new devices based on a coherent set of criteria. More research would be required to determine how this system works in practice.

When it comes to the depth of coverage, the Ontario regime is less generous than those countries (England, Norway, Italy and New Zealand) that cover the entire cost of assistive devices. At the same time, cost-sharing requirements are also part of the regimes in Germany, Australia and the Netherlands. More research would be required to determine the exact level of this cost-sharing for selected devices to determine the relative burden of cost-sharing across these jurisdictions. Within Canada, cost-sharing is the rule among provinces. There are three exceptions. In Saskatchewan, Manitoba, and New Brunswick, the devices are loaned to individuals from a pool at no cost to their respective residents.

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Appendix - Template for data collection and analysis

Canada (Ontario)

A) Regulatory framework *(highlight differences per device type if applicable)*
What is the governing legislation for the coverage of ATs? All jurisdictions in Canada have governing legislation surrounding the assistive devices programs. Most jurisdictions, including Ontario rely on their assistive devices programs to be administered by provincial departments. **(Schreiber and Wang, 2017)**
Are there human rights/disability/employment laws that influence coverage? Guided by the Ontario Human Rights Code. Prohibits actions that discriminate in areas of employment, housing, and services. The code prohibits actions that discriminate against a person based on protected ground (age, ancestry, disability, gender, sex, sexual orientation) in a protected area (housing, employment, services, professional associations). Devices covered by the program are intended to enable people with physical disabilities to increase their independence through access to assistive devices responsive to their individual needs. (MOHLTC, 2016). The coverage is influenced by the following laws: • *Ontario Disability Support Program Act, 1997, SO 1997, c 25, Sch B, General, O Reg 222/98, (Ontario Disability Support Program Act, 1997)* which outlines regulations for income support for persons with disability. • *Employment Supports, O Reg 223/98 , (Ontario Disability Support Program Act, 1997)* which outlines regulations for income support for persons with disability. • *Ministry of Health and Long-Term Care Act, RSO 1990, c M.26* – which according to the manual of the Assistive Devices Program, this act governs the program • *Regulation 225/98 - Administration and Cost Sharing* • *Regulation 562/05 - Prescribed Policy Statements*
What is the level of administration of coverage decision-making? National/regional/local? It falls under the mandates of two ministries under two different programs (Government of Ontario, 2018): • The Ontario Ministry of Health and Long-Term Care (MOHLTC) – Assistive Devices Program (ADP). Devices covered by the program are intended to enable people with physical disabilities to increase their independence through access to assistive devices responsive to their individual

needs. (Ontario Ministry of Health, 2016)

- The Ministry of Community and Social Services (MCSS) - Ontario Disability Support Program (ODSP) – Disability Related- Benefits and Extended Health Benefits. To provide coverage to ODSP benefit unit members for assessment fees and the consumer co-payment for the Ministry of Health and Long-Term Care's Assistive Devices Program (ADP). (Government of Ontario, 2005)

Do individual payers have flexibility in coverage decision-making? (distinguish between add-on coverage and general flexibility)

Coverage decisions are made at the provincial level in Ontario.

What is the role of NGOs? (note: is the role formalized or symptomatic?) (Government of Ontario, 2018)

A few volunteer and charity organization in Ontario assist individual users and their families pay their share for ATs. These organizations provide grants only; the review did not gather any information about other types of support provided by them. These organizations are:

- Easter Seals Ontario
- March of Dimes Ontario
- Warm Amps
- Kiwanis
- Lions Clubs

Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.)

Assisted technologies are not included as insured services under the Canada Health Act and therefore not part of universal health coverage under Canadian Medicare. As a consequence, the public funding or provision of assisted technologies is set by federal, provincial and territorial governments acting alone, largely through extended health benefit programs. In Ontario, eligibility includes any Ontario resident who has a valid Ontario Health card issued in their name and has a physical disability of six months or longer. **(Schreiber and Wang, 2017)**

B) Devices included

Mobility aids (e.g. wheelchairs, walkers, crutches)?

ADP helps cover the cost of mobility aids include: wheel chairs, walkers, crutches, wheeled walkers, pediatric walkers, and positioning devices. ADP also covers the cost of replacing a mobility aid as a result of changes in medical conditions, quality or size. **(Government of Ontario, 2016a)**

Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

Ontario's ADP program does not cover hospital beds or mattresses, stair lifts, or lifts.

Respiratory aids? (e.g. CPAP machines, oxygen support)

ADP funds respiratory aids including: continuous positive airway pressure (CPAP) machines, oxygen support, cardiorespiratory monitors used for sleep apnea, percussors and postural drainage boards for cystic fibrosis, auto-titrating positive airway pressure systems (APAP), and more. ADP also covers the cost of replacing a mobility aid as a result of changes in medical conditions or quality. **(Government of Ontario, 2016a)**

Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)

ADP provides funding to cover the cost of Audio, Visual, and communication aids include bone-anchored hearing aids, adaptive telephones, reading and writing devices. **(Government of Ontario, 2016a)**

C) Requirements for inclusion of devices in benefit catalogue

What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)* (Government of Ontario, 2016a)

Regulatory approval must be granted at the federal level in order for assistive devices to be sold in Canada. The Program will only list and provide funding assistance for Devices that meet the requirements set out in the ADP process Manual and are approved for listing by the Program.

Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list? (Government of Ontario, 2016a)

The ADP may consider listing a new type of product that is not currently represented in one of the Device categories listed in the ADP Manual if:
The product:

- Supports the ADP mandate to increase the Client's independence through access to assistive Devices responsive to their individual needs;
- Where applicable, has been tested for safety, has undergone manufacturer clinical trials with clear durability specifications, has user manuals and pricing details;
- Can be personalized and recommended based on an assessment by a healthcare professional;
- Is customized to address a disability;
- Is approved by Health Canada-F Funding is not available from other government programs;
- there is evidence-based supportive documentation showing that it is a breakthrough product that provides substantial improvement over comparable products and the proposed price of the product is comparable with prices in other provincial or federal jurisdictions; and
- Funding of the product is aligned with current government priorities. Funding is not available from other government programs;

- There is evidence-based supportive documentation showing that it is a breakthrough product that provides substantial improvement over comparable products and the proposed price of the product is comparable with prices in other provincial or federal jurisdictions; and
- Funding of the product is aligned with current government priorities.

The ADP will not consider listing a product if the product:

- Is not deemed to be cost-effective for ADP funding assistance;
- Is a common/mainstream product used by the general population;
- Will be exclusively used for therapy or treatment purposes;
- Will be exclusively used for a diagnostic or monitoring procedure;
- Is a home or vehicle improvement and/or modification;
- Will be exclusively used for work, education or recreation purposes;
- Will be used for cosmetic purposes only;
- Will be implanted within the body;
- Is required for daily self-care activities (e.g., transferring, dressing, toileting or bathing); Is to be used exclusively to address a safety need; or
- Is for short-term use.

The Program will remove a Listed Device where:

- the Listed Device is not cost-effective for the ADP; the Listed Device is not safe or reliable,
- the Listed Device is not utilized by Clients,
- the manufacturer/distributor is not abiding by the Policies and Procedures of the Program.
- the Listed Device is not supported by the manufacturer/distributor,

the Listed Device has been discontinued or voluntarily recalled, or Health Canada or the United States Food and Drug Administration has recalled the Listed Device.

(Especially if there is no HTA) **Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?**

Information included above.

How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

Once regulatory approval is granted, assistive device vendors have to apply to the provincial assistive devices programs to have a device listed as one of the publicly funded devices. Based on this review the specifics of this process was unclear. **(Schreiber and Wang, 2017)**

D) Eligibility *(highlight differences per device type if applicable)*

Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

Eligibility is determined by ADP. The applicant is able to work with a designated therapist to complete an ADP application form.
(Government of Ontario, 2018)

Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)*

To be eligible for ADP funding, the applicant must be an Ontario resident who has a valid Ontario Health card issued in their name and has a physical disability of six months or longer. Equipment cannot be required exclusively for sports, work or school. ADP does not pay for equipment available under the Workplace Safety and Insurance Board or to Group "A" veterans for their pensioned benefits. Additionally, there are specific eligibility criteria which apply to each device category. Most devices must be authorized by qualified health care professional registered with program.

Ontario only assess income for individuals applying to be considered under the Ontario Disability Support Program – Benefits and Extended Health Benefits program.
(Government of Ontario, 2018)

Is there (periodic) reassessment of eligibility required?

The information gathered in this review did not identify period reassessment of eligibility under ADP.

Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

In 2017, Ontario introduced Ontario's Employment Strategy for People with Disabilities. Even though the strategy does not directly fund Assistive Technologies, its goal is to reduce social and economic barriers to reduce the rate of unemployment for individuals with disabilities. The strategy helps individuals with disabilities by: providing them with work and training opportunities; providing support and training to employers; and increasing awareness and improving attitudes toward the talents of individuals with disabilities. **(Government of Ontario, 2017)**

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?
The Assistive Devices Program generally pays for up to 75% of the cost of approved assistive devices. In some cases, the Assistive Devices Program pays a fixed amount for a device or provides grants directly to a person for supplies. Payers are able to get additional funding from volunteer and charitable organizations to help cover their portion. The Ontario Disability Support Program can also help with

some of the costs that are not covered by the Assistive Devices Program.

The ministry will also pay for:

- An assessment for an assistive device funded by the Assistive Devices Program if there is no other source of funding for the assessment.
- Direct Payments (grants) for Supplies (ostomy supplies and insulin syringes) (Government of Ontario, 2005)
- Flat Rate Maximum Contributions respiratory aids, prosthetics, wheelchairs and ambulation aids, communication aids, hearing aids and visual aids
- 75% / 25% Funding Formula (enteral feeding, orthotics, pressure modification devices, and positioning devices.) (Government of Ontario, 2005)
- Lease Payments for High Technology Communication Devices

ADP will provide 100% coverage if the individual is receiving support from: Ontario Works, Ontario Disability Support Program and/or Assistance for Children with Severe Disability. **(Government of Ontario, 2018)**

Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

The Government of Canada provides disability tax credit (DTC) to individuals under the age of 18 and their caregivers. To be eligible, the individual must be restricted in at least one daily activity and the disability must be continuous for at least 12 months **(Canada Revenue Agency, 2018).**

How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

MCSS will cover the consumer contribution for the annual lease payments for ADP approved high technology communication devices up to the amount permitted under (the amount varies by device) ADP for recipients of ODSP. **(Government of Ontario, 2005)**

If the applicant is not approved for ADP funding for any reason, they are responsible for 100% of the cost. **(Government of Ontario, 2018)**

What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

Vendors interested in joining ADP must complete an application form and share it with MOHLTC. The ministry will then determine whether a vendor is approved to participate in the program or not. According to the review, there is no tendering process and vendors are approved based on the application form. The criteria to approve a vendor is not transparent. **(Government of Ontario, 2018)**

E) Access pathways

How is access triggered? Does the individual and/or the provider have to apply? To whom?

The individual with the help of an occupational therapist or a physiotherapist are able to apply for funding under ADP after determining which aid is suitable and finding a registered vendor. **(Government of Ontario, 2018)**

Who is responsible for procuring and maintaining the device?

The patient purchasing a device is responsible for directly contacting a vendor of interest. The patient will then contact MOHLTC for reimbursement. The patient is responsible for maintaining their device, however, MOHLTC provides maintenance funds under certain circumstances. **(Government of Ontario, 2018)**

Which devices are loaned and which are the property of the individual? Are loaned devices refurbished? Is there data on savings from this process?

This information was not found under the ADP. However, the ALS society of Canada Equipment Program provides funding for renting equipment. The program does not specify which equipment can be rented. **(ALS Canada, 2018)**

F) Data

Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

The review found data in an Auditors report on the volume of AT per category and the expenditure on AT by the statutory health system. However, the data was reported in 2008 and does not reflect the current status of the program.

ICES collects some data on ADP and it was last modified in 2016. From looking at the application form for ADP, I can tell that MOHLTC also collects data that could answer these questions, but we were not able to obtain them from my online research.

Auditor's report:
http://www.crto.on.ca/pdf/Legislation/Proposed_COI_Regulation/Appendix_4.1_AGR_2009.pdf

G) Policy (process)

Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

This information was not found.

Are there any recent/relevant political debates or policy documents/strategies?

1. Canada Revenue Agency. (2018, January 03). Disability tax credit. Retrieved from https://www.canada.ca/en/revenue-agency/services/tax/individuals/segments/tax-credits-deductions-persons-disabilities/disability-tax-credit.html
2. Mattison, C.A., Wilson, M.G., Wang, R. H., & Waddell, K. (2017). *Evidence brief: Enhancing equitable access to assistive technologies in Canada.* Hamilton: McMaster Health Forum, 7 June 2017.
3. McColl, M. A., Roberts, L., Miller, B., & Smith, E. (2015). *Policy governing support for mobility aids for people with disabilities in Canada.* Canadian Disability Participation Project and Canadian Disability Policy Alliance.
4. Hayes, A., Campo, M., Shirodkar, P & Surajbali, K. (2017). A Literature Review on Funding Models for Assistive Devices Program, Evidence Synthesis Unit Product #501. Government of Ontario, Ministry of Health and Long-Term Care.
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8. Government of Ontario. (2016a). Ministry of Health and Long-Term Care, Policies and Procedures Manual for the Assistive Devices Program. Retrieved February 28, 2018, from http://www.health.gov.on.ca/en/pro/programs/adp/policies_procedures_manuals/docs/pp_adp_manual.pdf
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11. Government of Ontario. (2018a). Ministry of Community and Social Services, Disability-related benefits: Coverage for assistive devices. Retrieved February 28, 2018, from https://www.mcss.gov.on.ca/en/mcss/programs/social/odsp/income_support/odsp_device.aspx
12. ALS Canada. (2018). Equipment. Retrieved 2018, from https://www.als.ca/support-services/inside-of-ontario/equipment/

Australia

A) Regulatory framework *(highlight differences per device type if applicable)*
What is the governing legislation for the coverage of ATs? Governing legislation in Australia is bifurcated: funding for those under 65 years old (in the majority of cases) is through the National Disability Insurance Scheme (NDIS) and for those who are 65 years and over (and those ineligible for the NDIS) by state and territory administered funding programs. **Under 65**: National Disability Insurance Scheme Act 2013 **≥ 65**: Disability Services Act 1986
Are there human rights/disability/employment laws that influence coverage? The National Disability Insurance Scheme Act 2013 and the Disability Services Act 1986 directly influence coverage. The Australian Human Rights Commission Act 1986 and The Commonwealth Disability Discrimination Act 1992 are interwoven, with both laws applying to aspects of disability rights and human rights. This also influences coverage **(programs include provision of AT/AD) e.g. emloyment; education; access to premises; and provision of goods services and facilities.** Under the Disability Discrimination Act 1992, a set of 'disability standards' are outlined and written into the Act. These include standards in the areas of employment, education, public transport services, access to premises, accommodation and the administration of Commonwealth laws and programs. Both Acts influence disability employment laws, requiring employers to make reasonable adjustments in work arrangements for their employees with a disability, to ensure they have equal opportunities in the workplace. **In Australia, tort law consists of both common law and, to a lesser extent, legislation. Tort law influences coverage (particularly in education and employment) by ensuring state governments and organisations are liable for breaches in their statutory duties (e.g. if a potential employee of the NSW Government has all the necessary attributes to fulfil a role they cannot be exluded on the grounds of hearing loss when reasonable adjustments can be made and their disability does not pose any danger when performing duties of the role).**
What is the level of administration of coverage decision-making? National/regional/local? This varies based on the overarching funding scheme, please refer to the accompanying report for further clarification.
Do individual payers have flexibility in coverage decision-making? (distinguish between add-on coverage and general flexibility) In Australia, in regard to our universal health coverage (Medicare) this does not apply, our AD/AT

programs (the NDIS and the state and territory programs) do not require options of add-on extra coverage and coverage decision-making is entirely the responsibility of the state or Commonwealth government. The NDIS was designed for choice and control; the consumer is provided an individual plan and funds to purchase services based on their lifestyle and eligibility. The new scheme is therefore more flexible than the previous welfare system in place. See answer in section D) Pricing, cost-sharing and procurement, for further details.

What is the role of NGOs? (note: is the role formalized or symptomatic?)

The role of NGOs' in the Australian context is supplementary. Several not for profit organisations exist, and provide modest equipment grants, however, they are not replacements to state and national funding bodies with relevant funding schemes responsible for supplying equipment.

An exception to this is in Western Australia, where state funding schemes outsource to Disability Sector Organisation Providers for the commission and administration of equipment/devices. These organisations do not manage the funding, however, are heavily involved in consultation activities and support coordination, more so than other states or territories.

NGOs' across the country are primarily in supportive capacities more so than acting as funding bodies, mainly focused on providing support for families, lifestyle choices and helping people navigate the aforementioned funding schemes.

Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.)

The nature of coverage in Australia is varied. State and national AD/AT schemes are funded through taxes. Private health insurance is not mandatory and each insurance plan will have differing levels of coverage for devices, if at all. Please refer to the accompanying report for more detailed information on coverage in Australia.

B) Devices included

Mobility aids (e.g. wheelchairs, walkers, crutches)?

A wide range of mobility aids are discussed throughout the accompanying report. There are varying funding schemes providing coverage in Australia (Table 1, p. 6-7 of report), with each of these stipulating different levels of coverage and varying devices. The provision of mobility aids is dependent on eligibility.

Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

A resident may be eligible for home aids, such as shower chairs, nonslip bath mats, grip equipment under the NDIS (refer to p. 14 of report). Home modifications can be partly funded, but there are significant gaps in service provisions. If funded by the NDIS, the delivery costs, and set up costs, should be covered.

Outside of the NDIS, for example, Department of Veterans Affairs (DVA) gold card holders living at home, will be eligible, through the Rehabilitation Appliances Program, to receive funding for a wide range of household aids, including adaptive devices such as modified vegetable chopping boards. However, DVA card holders residing in a Residential Aged Care Facility (RACF) are not entitled to the same equipment and a different schedule of items is provided through the Commonwealth Home Support Program.

The provision and coverage of household aids is greatly varied between funding schemes.

Respiratory aids? (e.g. CPAP machines, oxygen support)

Respiratory aids, in some states, come under the same funding schemes as AD/AT. However, other states/territories have separate funding programs for respiratory aids For example, in South Australia and Tasmania, oxygen and respiratory aids are funded under separate state funded programs, while other states and territories administer funding under programs operating within the cover.

Despite often being included under the same funding schemes as AD/AT, oxygen concentrators are more often defined as a medical device in other jurisdictions.

Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)

As mentioned, separate state and Commonwealth funded schemes may fund these aids in varying capacities. As listed in Table 1 of the report (p. 6-7), there are NGOs and community support, such as Auslan and Vision Australia, that can offer additional support in these areas.

C) Requirements for inclusion of devices in benefit catalogue

What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)*

The Therapeutic Goods Administration (TGA), a government agency, is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods.

Devices need to be approved and comply with Australian standards (www.standards.org.au), in particular, devices covered by Commonwealth funding will be required to comply and be approved by the TGA. Compliance with Australian standards (AS) or joint Australian/New Zealand (AS/NZS) standards may be voluntary or mandatory. Mandatory standards are law and there are penalties for supplying products that do not comply with them. However, there are some assistive devices that have no clearly defined Australian standards (e.g. some assistive communication devices, such as tablet computers for running speech pathology applications).

Third party certification, inspection and testing bodies assess whether a product conforms to an

Australian Standard. A list of mandatory standards and information on product testing is available at: www.productsafety.gov.au

Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

Due to the fact that AD/AT in Australia are covered by a wide range of publicly and privately funded sources, approval of devices is focused primarily on the safety aspects. Prior to approval, devices go through a rigorous testing and assessment process that each individual funding body will undertake which includes a strategic procurement plan (Layton et al. 2016).

Each individual funding scheme provides a schedule of items. However, there is little transparency as to why certain items are included/excluded and the AD/AT may be approved and compliant with Australian standards. This does not necessarily mean they will be covered by the funding source. For example, the Prostheses list produced by the Commonwealth contains a list of 1000 prosthetics that may be funded – however this list changes annually and whilst recreational prostheses are frequently included on this list (e.g. specialised prosthetic for running), more often than not the Commonwealth and state/territory funding schemes choose not to fund recreational prosthetics.

Source: Layton, W., et al. Quality, Choice and Outcomes in Assistive Technology (AT) Equipment Funding Schemes: A Procurement Case Study. *Health Syst Policy Res*. 2016, 3:1.

***(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?**

The TGA applies a risk-based approach to regulation. The risks involved with therapeutic goods can be divided into two types:

- Product risks: these risks are inherent to the product.
- Compliance risks: these risks are related to the risks involved if a manufacturer or sponsor fails to comply with legal requirements (either unintentionally or intentionally).

The TGA actively regulates both product risks and compliance risks.

How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

Devices will be included if they meet Australian standards and are approved by the TGA (see above) and/or at the discretion of the appropriate body (e.g. aids that may not be approved but pose no risk such as a talking computer).

D) Eligibility *(highlight differences per device type if applicable)*

Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise

(where from?)?

Eligibility is determined through clinical assessment by a suitably qualified and registered physician. Each funding scheme has varying requirements.

As an example, EnableNSW, a state-funded government agency, has developed clinical criteria (previously known as Prescription and Provision Guidelines) for each specific equipment category. The clinical criteria have been developed in consultation with expert clinicians and are designed to specify requirements in each AD/AT category. The criteria provide a basis for consistent and transparent decision making. The listed items are not exhaustive and EnableNSW reserves the right to make the final decision regarding the provision of equipment that is not specifically included or excluded in the clinical criteria for a particular equipment category.

Other state funded schemes provide similar outlines for clinical assessment to ensure consistent standards are met in terms of level of impairment.

Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)*

For Part A (NDIS), this is not clearly defined as to what they are eligible for on an individual basis. For Part B (over 65), refer to Table 2 of the report; this provides a comprehensive list of eligibility and ineligibility criteria for each scheme.

Is there (periodic) reassessment of eligibility required?

For someone to be deemed eligible for the funding schemes detailed in Table 1 of the accompanying report, the initial clinical assessment must verify that the injury or disability is chronic and permanent. Non-permanent injuries that require AD/AT are funded through separate loan programs, often hospitals are required to provide the equipment.

The rollout of the NDIS has meant periodic reassessment of eligibility, as those who were eligible for the NDA may no longer be eligible for the new NDIS program (e.g. those over the age of 65).

Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

For education and employment, the Disability and Discrimination Act 1992, [Part 2, Division 1 and Division 2] stipulates that discrimination on the grounds of disability in employment and education is against the law and reasonable adjustments can be made and funded by the Commonwealth. The funding provisions to improve access for disabled individuals in the workforce are adequate, however, pathways are complex and the lack of transparency as to the amount and timeframe of reimbursement may deter employers (particularly small businesses) from hiring suitably qualified disabled persons [in particular Clause 21A (Exception-inherent requirements) or Clause 21b (Exception-unjustifiable hardship) of the Act].

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*
Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)? Cost-sharing in the form of gap payments for assistive devices is only applicable for those with private health insurance, which is not a mandatory requirement in Australia (although strongly encouraged). Cost-sharing within the Commonwealth and state/territory funding schemes is means tested on a case by case basis with some states. For example, Tasmania only provides funding to those receiving government welfare payments (i.e. Centrelink benefit recipient). The NDIS payment scheme is divided into three categories; core (support for daily living), capital (investment like assistive devices), and capacity building (support enabling independence). Capital supports are usually restricted to specific items identified in the plan but most items are negotiable between providers and consumers. There are price limits on supports and services, i.e. "Where price limits apply, prices charged to participants must not exceed the price level prescribed for that support in the Price Guide, though less may be charged. No other charges are to be added to the cost of the support, including credit card surcharges, or any additional fees including 'gap' fees, late payment fees or cancellation fees." (https://www.ndis.gov.au/html/sites/default/files/documents/Provider/201617-vic-nsw-qld-tas-price-guide.pdf) Generally, a participant is not required to contribute to delivery payments, or service that have been included in the plan. The NDIS covers the full cost of the provision of the support considered reasonable. In most cases, a participant is free to choose a more expensive option but at their own expense, if it is not considered reasonable and necessary.
Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices? Some Australian residents will be eligible for tax rebates. If for example, a person with hearing impairment required specialized equipment in their profession, this would be tax deductible. However, there are government funding schemes that offer grants for particular equipment relating to education and employment.
How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need? Prices of devices are determined by the manufacturer or pharmaceutical company developing or supplying the device. Patients receive funding for equipment that is approved by Australian standards through the TGA, and listed on the schedule of equipment (this varies slightly between each specific funding body).

More expensive devices are funded based on clinical need, and if the reasons for choosing the product can be justified by the treating physician, funding may be received. Schedules of equipment (see below for EnableNSW example) list approved products (including cheapest option and most expensive) within a specified category, from a range of suppliers.

Category No.	Category Description	Supplier Name	Brand Name of Product	Supplier Product Code	Product Name	Colour	Safe Work Load
21.10	Walking Frame, four wheels, folding, adjustable height	Watercomfort Company	CareQuip	2967Bu	Seat Walker - Adventurer Hand brakes - lockable. Height adjustable handles.	Metallic burgundy	130
21.10	Walking Frame, four wheels, folding, adjustable height	Watercomfort Company	CareQuip	2727Bu	Seat Walker - Scout Large 8" castors - mobility for OUTDOORS. Fold backrest. EASY FOLDS with Vinyl bag attached. Hand brakes - lockable. Height adjustable handles.	Metallic burgundy	130
21.10	Walking Frame, four wheels, folding, adjustable height	Watercomfort Company	KCare	KA365 Bu	Seat walker, Kcare - Hand brakes, curved backrest, 6" wheels, Burgundy	Burgundy	120
21.12	Walking Frame, bariatric, four wheels, folding, adjustable height	Astris Lifecare	Care Quip	2977	Galaxy Seat Walker, Adjustable,HD		200
21.12	Walking Frame, bariatric, four wheels, folding, adjustable height	Aidacare Pty Ltd	My Mobility	WAF699400	Seat Walker - K Care - Maxicare 225kg - Height Adjustable, Hand Brakes, Padded Backrest, Basket - 8" Whls	Red	225
21.12	Walking Frame, bariatric, four wheels, folding, adjustable height	Watercomfort Company	Carequip	2937Bu	Seat Walker - Caravan. WIDE Reinforced frame. Hand brakes - lockable. Height adjustable handles.	Metallic burgundy	150
21.14	Walking Frame, forearm support, folding, adjustable height	Aidacare Pty Ltd	K Care	WAF704400	Forearm Walker - K Care - Walking Tutor (Small) 4 Wheeled - 600-790mm		60
21.14	Walking Frame, forearm support, folding, adjustable height	Aidacare Pty Ltd	K Care	WAF709200	Forearm Walker - K Care - Walking Tutor (Med) 4 Wheeled - 670-960mm		80
21.14	Walking Frame, forearm support, folding, adjustable height	Aidacare Pty Ltd	K Care	WAF708900	Forearm Walker - K Care - Walking Tutor (Large) 4 Wheeled - 850-1350mm		100
21.14	Walking Frame, forearm support, folding, adjustable height	Freedom Health Care	Freedom Healthcare Walking Tutor Heavy Duty	BRO212	Gutter Arm, Light Touch Brake, Folding, Rear Forked Walker, Bariatric, Oval tube.		180
21.15	Walking Frame, bariatric, forearm support, adjustable height	Astris Lifecare	Care Quip	2805	Forearm Walkier, Adjustable, HD		170
21.15	Walking Frame, bariatric, forearm support, adjustable height	Watercomfort Company	KCare	KF36010	Maxi Tutor with Gutter, 4 wheels	Black	250

What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

Unable to answer as to the individual contracts.

According to Layton et al (2016) procurement plans through jurisdictional AD/AT funding programs in Australia (in particular VIC and SA) embarked on a strategic procurement plan for low cost /high volume non-customised AD/AT, intending to manage costs due to demand projections and increasing pressure on a capped budget. This has resulted in the procurement process effectively limiting choice of AD/AT devices to a subset of quality, repairable and re-issuable AD/AT devices.

E) Access pathways

How is access triggered? Does the individual and/or the provider have to apply? To whom?

Through verified, approved and accredited providers, access is triggered through the treating physician and patient upon submitting an application to the relevant funding body.

Who is responsible for procuring and maintaining the device?

The funder is responsible for procuring the device and providing reasonable funding to maintain and service equipment. Individual patients, however, are expected to maintain and store equipment appropriately and if the supplier of the equipment deems the breakage or need for servicing is due to

negligence rather than everyday wear and tear, funding will not be provided for servicing and maintenance.

Where to contact for the maintenance and servicing of a device will vary depending on the individual funding scheme or piece of equipment (see EnableNSW as an example)

Repairs and Maintenance

Requesting repairs

Who to contact

EnableNSW provides funding for servicing and reasonable repairs to items supplied by us. Please see the below table for guidance about who to contact for repairs.

Equipment Type	Examples	Who to call
Prosthetic limbs	Upper and lower prosthesis	Your prosthetic service provider
Home oxygen devices	Oxygen concentrators Oxygen cylinders	Supplier of the machine. See sticker on device for phone provider
Other respiratory devices	CPAP* Bi-level* Suction units Heated humidifiers Ventilators *Please note we may need to confirm your pressure settings with your prescriber	EnableNSW T: 1800 362 253 Mon - Fri 9am-5pm
Communication	Speech generating devices Blindness and low vision aids	EnableNSW T: 1800 362 253 Mon - Fri 9am-5pm
Mobility	Manual wheelchairs Power wheelchairs Walking frames Strollers	EnableNSW T: 1800 362 253 Mon - Fri 9am-5pm

[Source: http://www.enable.health.nsw.gov.au/services/repairs]

Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

Although this will vary case by case, the majority of devices are essentially 'loaned' to the individual for the duration of their life or duration of needing the device (e.g. if the individual's clinical or functional needs change and a different type of equipment is required). Data on the savings of the refurbishment process is not freely available to the public.

It can be assumed that the savings are significant; Commonwealth and state/territory funding schemes limit the supply and procurement of devices according to a set of justifiable quality measures, and ensures items provided to individuals are durable, refurbishable and will be re-issuable for the longest amount of time possible whilst still meeting rigourous quality and safety criteria.This ensures budgets are met and patients are still receiving high quality, safe products (Layton et al, 2016).

The exception to this is with prosthetics, which become the property of the individual due to the fact these items need to be customised for the individual, although there are prosthetic 'recycling' programs and parts can and may be reused when and if returned.

F) Data

Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

Unfortunately, there is no information on the above.

G) Policy (process)

Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

Unable to answer. Datasets are fragmented or unavailable in Australia. Schedules of included devices change annually, however, information as to the costing and reasoning behind these changes is unavailable publicly.

Are there any recent/relevant political debates or policy documents/strategies?

1. **Queensland Competition Authority:** Price Disparities for Disability Aids and Equipment (2014) [http://www.qca.org.au/getattachment/a98aac78-d791-4718-acbd-756195580892/Final-Report-Medical-and-Disability-Aids-and-Equip.aspx]
2. **Prisoners excluded from the NDIS:** (2017) [https://theconversation.com/prisoners-are-

excluded-from-the-ndis-heres-why-it-matters-73912]

3. **NDIS Strategy 2010-2020:** (2011) [https://www.dss.gov.au/]

There are multiple documents, news articles and reports which discuss the problems with the NDIS rollout, ranging from human rights violations to administration and staff training issues. The complaints directed towards the NDIS has been the source of controversy and political debate.

Germany

A) Regulatory framework *(highlight differences per device type if applicable)*

1) What is the governing legislation for the coverage of ATs?

- Social Code, Book V (SGB V): Definition of basic entitlements
- Federal Ministry of Health: can exclude ATs with a small or disputed therapeutic benefit or a low selling price´

2) Are there human rights/disability/employment laws that influence coverage?

According to the Social Code Book (§33): insured persons have the right on the provision of ATs necessary in the individual case to ensure treatment, prevent the threat of disability or, compensate for disability. ATs must not be a general issue of everyday life or must not excluded by this law.

3) What is the level of administration of coverage decision-making? National/regional/local?

In general, national level through the *National Association of Statutory Health Insurance Funds*

4) Do individual payers have flexibility in coverage decision-making? *(distinguish between add-on coverage and general flexibility)*

General: No flexibility, if medically necessary
Add on coverage: ATs not listed in the benefit catalogue could be covered due to case by case decision making

5) What is the governing legislation for the coverage of ATs?

Regulation is largely delegated to self-governing associations of sickness funds and provider associations together representing the Federal Joint Committee.

Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA):

- Broadly determines the benefit package by issuing directives on the provision of ATs regarding adequate, expedient and cost-effective care
- The directive on ATs broadly defines the situation in which patients are entitled to ATD benefits and limits the prescription of ATDs to the following cases: Ensuring the success of medical treatment, preventing threatened health damage, preventing the health endangerment of a child, and avoiding or reducing the risk of long-term care.
- Establishes fundamentals of the AT benefit catalog ('Hilfsmittelverzeichnis')

National Association of Statutory Health Insurance Funds (GKV-Spitzenverband):

- Defines and administrates the benefit catalog (a quasi-positive list) which lists individual products that can be provided at SHI expense (products are included in one of 33 categories)

Sickness funds: If a certain AT is not included in the SHI benefit package, sickness funds

decide on a case-by-case basis whether to provide the ATD

6) Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.)

- Mandatory insurance for all citizens and permanent residents: provided by two systems 1) competing, not-for-profit, nongovernmental health insurance funds ("sickness funds") in the statutory health insurance (SHI) system (approx. 86%); 2) substitutive private health insurance (PHI) ((approx. 11%); ***subsequent information in this template pertains only to the SHI system if not otherwise specified.***
- SHI: (1) mandatory for employed citizens earning less than 59,400 € in 2018 (their nonearning dependents and other groups such as pensioners, students) → compulsory contributions levied as a percentage of gross wages (14.6% of wage-related income divided equally between the employee and the employer) up to a ceiling; nonearning dependents are covered free of charge; (2) Voluntary for individuals whose gross wages exceed the threshold and previously SHI-insured self-employed
- PHI: (1) Mandatory for self-employed, civil servants; (2) Voluntary for individuals whose gross wages exceed the threshold and previously SHI-insured self-employed

B) Devices included

1) Mobility aids (e.g. wheelchairs, walkers, crutches)?

Crutches, vehicles for the sick and disabled, general mobility aids, ortheses, prostheses, standing aids, medical shoes, therapeutic mobility devices

2) Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

Bathroom devices, incontinence aids, nursing products, auxiliary seats, stoma articles

3) Respiratory aids? (e.g. CPAP machines, oxygen support)

Inhalation and respiratory aids

4) Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)

Devices for the blind, hearing aids, communication aids, optical aids, aids for adaption, aids for application, eye prostheses,

- ➔ Limited benefit catalogue, based on visual acuity (only covered above a certain degree of disability).

C) Requirements for inclusion of devices in benefit catalogue

1) What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)*

- Most ATs are classified as medical devices and are thus covered by the Medical Device Directives (and the succeeding Medical Device Regulation, adopted in 2017)
- Prerequisite to enter the European market has been the European Conformity (Conformité Européene [CE]) marking assigned by one of the Notified Bodies (an entity accredited by the corresponding EU Member State)
- Criteria for obtaining the CE mark vary by risk level of the respective device
- CE mark does not require a profound demonstration of effectiveness based on scientific clinical data in any case

2) Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

No, except ATs used within a procedure. In those cases, the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) performs a benefit assessment before including the AT in the benefit catalog.

3) *(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?

- National Association of Statutory Health Insurance Funds decides on inclusion of technical performance and safety (CE-mark), quality and may additionally defines indication-based quality requirements
- It can commission the Medical Service of SHI to check technical performance and safety, compliance with specific quality specifications, and if necessary proof of medical benefit
- If the AT is part of a procedure, the Federal Joint Committee performs a benefit assessment before including the AT in the benefit catalog

4) How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

Request of manufacturer to the National Association of Statutory Health Insurance Funds

D) Eligibility *(highlight differences per device type if applicable)*

1) Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

- All individuals under social health insurance are eligible for ATs
- Prerequisite: (1) Physician's prescription on individual level; (2) Provision with AT is

necessary to ensure success of treatment and prevent or compensate disabilities (unless these devices are consumer applications of daily use)
- Sickness funds approve the application in general
- Sickness funds can obtain expert advice concerning a patient's application.

2) **Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? (for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)**

- *Eligibility generally defined in the Social Code, Book V*
- *Implementation through the National Association of Statutory Health Insurance Funds; Criteria:* all individuals under social health insurance are eligible for ATs that are necessary to ensure success of treatment and prevent or compensate disabilities unless these devices are consumer applications of daily use
- Provision with visual aids is restricted by age and indication (SGB V and G-BA directives
- *Provision with hearing aids is restricted by indication*

3) Is there (periodic) reassessment of eligibility required?

Reassessment of eligibility in the case of first or renewed diagnosis or treatment decision appears medically necessary

4) Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

No

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

1) Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?

- National reference pricing system for incontinence products, hearing aids, visual aids, inserts and ATs for compression therapy
- Individual contracts between insurance fund and AT provider
- Co-payments
  (1) 10% (minimum 5€, maximum 10€); differences between consumable and non-consumable assistive devices (if consumable: 10% of overall cost, but maximum 10€ per month);
  (2) If patients choose higher priced products than the one set in the reference pricing system or in individual contracts between their insurer and the AT provider, they have to cover the difference between the reimbursement limit set by the sickness funds 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

- Exemptions: for specific population sub-groups
  (1) children up to the age of 18 years, low-income or high-need patients
  (2) Patients whose co-payments exceed 2% of gross household income are exempted from further co-payments. The threshold for patients with a chronic disease is 1%.
- Provider of ATs (i.e. persons of institutions authorized to supply assistive technologies) must submit a general cost calculation to the sickness funds; especially in the case of expensive ATs patients an application is necessary for the provision of an assistive device to the sickness fund along with the prescription, which must attest the medical need for the device
- Co-insurances regarding co-payments necessary

2) Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

No tax deductions

3) How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

- Patients must cover the difference between the reimbursement limit set by the sickness funds 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
- irregular adjustment of prices

4) What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

1) National Reference pricing for 5 groups (2018) of ATs
2) Types of contracts to procure ATs:
   a) sickness funds and their associations issue tenders for contracts with providers of ATs, ensuring economic efficiency and quality of care (e.g. for low-cost devices such as incontinence pads)
   b) if no tenders are issued, the partners conclude contracts according to the specific details of AT care; sickness funds must 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 an adequate 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)

→ Precondition for all three types of contracts: a negotiated price has to be lower than the existing reference price.
While the reference pricing system is valid for everyone with social health insurance, contracts are valid for the insured of the respective sickness funds.

E) Access pathways

1) How is access triggered? Does the individual and/or the provider have to apply? To whom?

- In the case of expensive ATs 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 general patients can choose between providers that are contractual partner of their sickness fund (exceptions possible if patients have a legitimate interest)

2) Who is responsible for procuring and maintaining the device?

Sickness funds and their contractual partners

3) Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

Devices are generally loaned (especially bigger devices); sickness fund is responsible for necessary refurbishment

F) Data

1) Are there reliable data on:

- volume of AT per category? (optimally longitudinal) – No (individual sickness funds publish periodic reports on this)

- expenditure on AT by the statutory health system? – Only on an aggregate basis by DESTATIS, the German Statistical Authority (individual sickness funds publish periodic reports on this)

- out-of-pocket spend (cost-sharing + direct payments)? – No

G) Policy (process)

1) Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

No major changes

2) Are there any recent/relevant political debates or policy documents/strategies?

Not particularly. The periodic reports on utilization mentioned in F1 have repeatedly shown regional variations, but no major actionable points have been raised so far.

Italy

A) Regulatory framework *(highlight differences per device type if applicable)*
1) What is the governing legislation for the coverage of ATs? The Ministerial Decree of 27 August 1999, n. 332 sets the rules that explain in detail who and why/when has the right to receive an assistive technology and the procedure to obtain it. In addition to the general principles, it also contains the list of these ATs accompanied by a code, technical / functional characteristics and price. In order to receive the ATs it is necessary to have a medical prescription and the authorization from the Local Health Authority where the person is resident. Other relevant laws: Law 102/92 on the assistance, inclusion and rights of persons with disabilities Law 68/99 on the rights of persons with disabilities in employment
2) Are there human rights/disability/employment laws that influence coverage? If the working capacity of a person is reduced by at least one third (33%) due to chronic or permanent illnesses, physical, mental or intellectual, that person can receive economic and medical support (art. 38 of the Constitution and Law 102/2009). According to the percentage of disability, the person can receive different benefits. Also, fundamental rights are elaborated in Law 102/92 on the assistance, inclusion and rights of persons with disabilities.
3) What is the level of administration of coverage decision-making? National/regional/local? Regional legislation has the task of organizing and providing the essential assistance for the protection of health through Local Health Authorities ("ASL"), which are present in every city where the person is resident. ***From the Commonwealth Fund's Health Systems profile on Italy:*** *"The 19 regions and two autonomous provinces have the responsibility to organize and deliver health services through local health units.* ***Regions enjoy significant autonomy in determining the macro structure of their health systems.*** *Local health units are managed by a general manager appointed by the governor of the region, and deliver primary care, hospital care, outpatient specialist care, public health care, and health care related to social care. (…)* *Under the Italian constitution,* ***the central government (…) defines a national statutory benefits package to be offered to all residents in every region.*** *Regions can offer services not included [in the national positive list/benefit catalogue] but must finance them themselves.* *(https://international.commonwealthfund.org/countries/italy/)*

4) Do individual payers have flexibility in coverage decision-making? *(distinguish between add-on coverage and general flexibility)*

Regions can offer services not included [in the national positive list/benefit catalogue] but must finance them themselves (see point 3).

It is the doctor who prescribes the AT that has the flexibility to choose which devices are appropriate. The only flexibility that the patient has is that he/she can request an AT which has the same functional characteristics of the one prescribed by the doctor, but with some add-on or special feature, and pay the difference in price.

5) What is the role of NGOs? *(note: is the role formalized or symptomatic*

No formalized role.

6) Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.))

From the Commonwealth Fund's Health Systems profile on Italy: *"The Italian National Health Service (Servizio Sanitario Nazionale, SSN) was set up in 1978, with universal coverage, solidarity, human dignity, and health needs as its guiding principles. It is regionally based and organized at the national, regional, and local levels. (…) Under the Italian constitution, the central government controls the distribution of tax revenue for publicly financed health care. (…)*
The National Health Service (NHS) covers all citizens and legal foreign residents. Coverage is automatic and universal. Since 1998, undocumented immigrants have access to urgent and essential services. Temporary visitors receive health services by paying for the costs of treatment."
(https://international.commonwealthfund.org/countries/italy/)

Registration to the SSN is mandatory for all the Italian and foreign citizens living in Italy and it is financed through taxes.

B) Devices included

1) Mobility aids (e.g. wheelchairs, walkers, crutches)?

Included in List n. 2 of the Tariff Catalogue ("Nomenclatore Tariffario"; List 2: mainly off-the-shelf products). The prices of the devices in this list are not reported because the Local Health Authorities have the right to directly purchase the products through tenders in order to define a cheaper price in relation to the quality of the product.

2) Household aids (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)?

Included in List n. 2 ("mainly off-the-shelf products") of the Tariff Catalogue. The prices of the in this list are not reported because the Local Health Authorities have the right to directly purchase the products through tenders in order to define a cheaper price in relation to the quality of the product.

3) Respiratory aids (e.g. CPAP machines, oxygen support)? Included in List n. 3 (“mainly products with critical maintenance needs”) of the Tariff Catalogue. Prices set by the Ministry of Health.
4) Audio, Visual and Communication aids (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)? Included in List n. 1 (“mainly custom-made or highly personalized equipment) of the Tariff Catalogue.
C) Requirements for inclusion of devices in benefit catalogue
1) What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)* Most ATs are classified as medical devices and are thus covered by the Medical Device Directives (and the succeeding Medical Device Regulation, adopted in 2017; see next paragraph for more detail). To be sold on the markets of the EU, European Economic Area or Switzerland, medical devices need to obtain a certificate of conformity to specific rules (Conformité Européene or CE mark) from a notified body. A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. The European Commission publishes a list of such notified bodies. For an example, see TÜV Rheinland (site in english: https://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html) The new EU regulation on MDs is in effect since May 2017 (Medical Device Regulation 2017/745, MDR). In line with its preceding EU framework for the market approval of MDs (Directives 90/385EEC, 93/42/EEC and 98/79/EC), it mainly addresses the issues of risk and functionality for devices aiming to enter the EU market. Depending on its intended purpose and invasiveness, a MD will be assigned to a risk class; different approval requirements apply depending on class.
2) Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list? Despite the fact that HTA is established practice in Italy (mostly at regional level) for drugs and devices, there does not seem to be much activity on assistive technologies (see main report, annexes).
3) *(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list? Not systematically. However, quality may influence tendering prices where applicable (see above). Furthermore, there seems to be an increasing realization of need to adopt evidence-based practices with respect to all aspects of the AT service delivery process (see a relevant framework

http://www.mdpi.com/2227-7080/4/3/31).
4) How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism) Manufacturer request.
D) Eligibility *(highlight differences per device type if applicable)*
1) Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)? Eligibility is determined at individual level. A prescription must be drawn up by a relevant medical specialist (or a team, for instance in the case of rehabilitation and mobile aids) of the National Health Service (employee or contract), following an evaluation of the person's "disability" and "functioning". This considers bodily functions and structure but also activities and environmental factors. The prescription must then be approved by the Local Health Authority of residence. The local health authority may ask for additional evidence if the prescription's appropriateness is in doubt.
2) Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)* There are clearly defined criteria, reported above in A2 and D1: If the working capacity of a person is reduced by at least one third (33%) due to chronic or permanent illnesses, physical, mental or intellectual, that person can receive economic and medical support (art. 38 of the Constitution and Law 102/2009). According to the percentage of disability, the person can receive different benefits. Citizens aged between 18 and 65 can be recognized as disabled, with congenital or acquired challenges, or with mental insufficiencies deriving from sensorial and functional defects. Those under the age of 18 are recognized as disabled only if they have persistent difficulties in carrying out their age-related tasks and functions. The same requirement applies to those over 65, for whom the recognition of invalidity is a prerequisite for granting the accompanying allowance. During the individual evaluation of eligibility, bodily functions and structure but also activities and environmental factors are considered.
3) Is there (periodic) reassessment of eligibility required? Depending on the condition/permanence of disability (and thus, type of AT).
4) Are there significant provisions and pathways of determining eligibility in the context of employment and/or education? Inversely, the parameter for the identification of the percentage of civil disability is the generic working capacity. Minors and over 65s are excluded from the work legal system therefore the criteria become instead the persistent difficulty in carrying out the tasks and functions proper to their age.

ATs that are related to functioning that influences working life are provided in the system decsribed above. Adaptations of the workplace to enable accessibility and working conditions for disabled persons are the responsibility of the employer. For ATs within the educational context responsibilities are shared between schools and local health authorities (e.g. school books must be available in digital format etc.). Similarly to the employment concept, if a student needs an AT for personal use, this is provided by the SSN, if the device pertains to school life specifically (e.g. a ramp or stair lift at school), it is the responsibility of the school.

Disabilities resulting directly from work accidents are usually subject to broader coverage and higher reimbursement levels.

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

1) Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?

If the patient is disabled for more than 33% than he/she has the right to receive the AT for free. The patients can choose more expensive alternatives than the ones in the Nomenclatore Tariffario and have to pay the difference out of pocket.

2) Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

Those who need ATs not included in the positive list need to pay out of pocket and can then file for reimbursement, usually partial (and decided on an ad hoc basis), through a number of national or regional schemes (e.g. a national fund for removing architectural barriers, regional funds for family support etc.).

A reduced VAT (4% cinstead of 21%) or tax credits may be available for some types of products not covered in the positive list. A medical attestation on their relation to a disability is required.

4) How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

Prices are determined by the Ministry of Health. The last revision of the Tariff Catalogue was the 12th of January 2017, while the one before than was the 27th of August 1999.
Patients do have to pay the difference in price if they choose a more expensive version of the AT that is prescribed to them.

5) What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

The Local Health Authority has to procure the AT for the patient. For the ATs in List n. 1-3 of the Tariff

Catalogue, prices are set and the Local Health Authorities procure them from the manufacturing companies. For the ATs in List n. 2, Local Health Authorities procure them through tenders.

E) Access pathways

1) How is access triggered? Does the individual and/or the provider have to apply? To whom?

To obtain the AT the individual has to consult a doctor in order to assess the need of the AT. This can be a general practitioner, who then has to refer the patient to the specialist relevant to their disability. Then the procedure follows these steps: the specialist(s) evaluate the type and level of disability and issue a prescription, which is approved by the Local Health Authority of residence of the citizen.

Depending on the type of AT, citizens are then free to choose their supplier and get reimbursed up to the tariff (for custom devices) or the devices are procured and delivered directly by the local health authority (other device types).

2) Who is responsible for procuring and maintaining the device?

This depends on the Tariff list the AT belongs to (see also E1). The Local Health Authority (LHA) is responsible for procuring the device in most cases, with the exception of personalized devices.

The repair of a device under warranty will be provided by the manufacturing company from which the LHA procured it, but is a responsibility of the patient to contact the company. While for the devices in List n. 2 of the Tariff Catalogue, the patient will have to contact the supplier of the device.

For all the other cases in which the devices are not covered by warranty, in the Tariff Catalogue are indicated which repairs are to be borne by the ASL and which not.

3) Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

As a general rule, the ownership of the device is the user who has been granted it. Exception are the devices of the List n. 3 of the Tariff Catalogue, which are granted on loan for free use.

F) Data

1) Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

We did not identify these data points readily available. Due to the decentralized structure of the system requests may have to be issued to the individual regional and/or local health authorities.

G) Policy (process)
1) Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices? No.
3) Are there any recent/relevant political debates or policy documents/strategies? In the past few years there were several debates about the nature of the Tariff Catalogue. Since it had never been updated after its release in 1999, the prices of ATs were high despite the fact that thanks to new technologies and developments their real value is lower. For example, if an individual wanted to purchase a wheelchair on their own, they would have paid € 132, while the same wheelchair would cost the Local Health Authority € 300. Finally, in January 2017 a new Ministerial Decree was released that updated the current Tariff Catalogue and procurement procedures of ATs. Another current debate is on procurement time of ATs. It is stated by the regulation that the Local Health Authority should procure and provide the AT to the patient within 20 days from the approval of their request. However, at least in the south of Italy, reality is different: patients often need to wait even 2-3 months before receiving their ATs.

Netherlands

A) Regulatory framework *(highlight differences per device type if applicable)*

1) What is the governing legislation for the coverage of ATs?

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 Wlz only covers AT for individuals living 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;
- WIA and Participation Act (below)

2) Are there human rights/disability/employment laws that influence coverage?

Act for Employment and Income According to Employment Capacity (WIA) and Participation Act: The Employees Insurance Administration Office (UWV) has a central role in relation to AT for work/employment. Generally, if medical devices are needed to participate in the workplace or in school, the UVW can (partially or in full) reimburse any needed adaptations and devices. We will not systematically discuss this option in the rest of this template due to limited information.

3) What is the level of administration of coverage decision-making? National/regional/local?

Zvw/Wlz: National level; WMO (municipal level)

4) Do individual payers have flexibility in coverage decision-making? *(distinguish between add-on coverage and general flexibility)*

There is some flexibility:

- Zvw: although a standard package exist (see below), the ATs are not listed individually, but rather described functionally: e.g. there is 'material for absorbing urine' instead of 'diapers'. This leaves room for insurers to purchase different products and differ in what they offer.
- Wmo: 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.

5) What is the governing legislation for the coverage of ATs?

- 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.
- WMO: Each municipality has its own regulations (also see above)

6) Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.))

- Zvw: mandatory insurance scheme covering all citizens for curative care (funded by community-rated premiums and income-dependent contributions)
- WMO: automatically through taxes/residency in a municipality
- Wlz: mandatory insurance scheme covering everyone who is legally residing or employed in the Netherlands for long term care (this act applies when people are in nursing homes, otherwise the WMO will be the

B) Devices included

5) Mobility aids (e.g. wheelchairs, walkers, crutches)?

AT provided under the WMO generally includes mobility/walking supports such as wheelchairs, scooters, adapted bicycles (also shared taxi services when possible)

Recent developments have led to the exclusion of certain ATs: for example, walkers, crutches, special chairs are not reimbursed anymore by any of the schemes. However, there are VHI policies available to cover this. (also see G1)

6) Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

Mostly covered by the WMO: home adaptations e.g. raised toilet seats, adapted bathrooms, stair-lifts (also coverage of costs for moving to an adapted home).

7) Respiratory aids? (e.g. CPAP machines, oxygen support)

Inhalation and respiratory aids are all provided under the Zvw, including CPAP, MRA machines, nebulizers, oxygen support, etc)

8) Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)

Devices for the blind, hearing aids, communication aids, optical aids, aids for adaption, aids for application, eye prostheses (all under the Zvw). Glasses/contacts are usually not covered.

C) Requirements for inclusion of devices in benefit catalogue

5) What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)*

- Prerequisite to enter the European market has been the European Conformity

(Conformité Européene [CE]) marking assigned by one of the Notified Bodies (an entity accredited by the corresponding EU Member State)
- Criteria for obtaining the CE mark vary by risk level of the respective device
- CE mark does not require a profound demonstration of effectiveness based on scientific clinical data in any case

6) Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

Not by a central body, but insurers are supposed to evaluate effectiveness (see below)

7) *(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?

- The insurer must assess whether a new assistive device fits the functional description of the standard package (regulated in par. 1.4 of the medical devices regulation).
- Insurers also have to assess whether a device meets the legal requirement of being "state of the art" and of proven effectiveness.

8) How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

See above (the medical device itself will not be listed in the standard package of care as reimbursed categories are described by function).

D) Eligibility *(highlight differences per device type if applicable)*

5) Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

- Under the ZVW, the insured or (para)medical professional treating the insured person makes a request for an AT. The Zorginstituut has issued a document describing 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, hoyers etc), while long term use falls under the Social Care Act. 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.
-

6) **Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? (for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)**

Depends on scheme, see above

7) Is there (periodic) reassessment of eligibility required?

Reassessment of eligibility in the case of first or renewed diagnosis or treatment decision appears medically necessary, and depends on guidelines and regulations of insurers and municipalities.

8) Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

No

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

5) Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?

- 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.

6) Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

There may be some additional local support available for vulnerable group depending on municipality

7) How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

- Zvw/WMO: Prices are established through contracting.
- Reimbursement limits: generally, all depends on the insurance policy and any VHI coverage that a patient has with his/her insurer. In general, patients must cover the difference between the reimbursement limit set by the insurer 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. But VHI policies exist that enable a free choice.

8) What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

Contracts are mostly based on tendering and negotiations (which does not mean patients necessarily have to opt for these selectively contracted devices (see G2)

E) Access pathways

4) How is access triggered? Does the individual and/or the provider have to apply? To whom?

Yes, generally individuals need to apply (WMO/ZVW/Wlz) see under eligibility.

5) Who is responsible for procuring and maintaining the device?

Insurers/municipalities and their contractual partners

6) Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

Devices are generally loaned (especially bigger devices); payer is responsible for necessary refurbishment

F) Data

2) Are there reliable data on:
The GIP databank has users, cost and volumes of devices under the Zvw population. https://www.gipdatabank.nl/databank and https://www.staatvenz.nl/kerncijfers/hulpmiddelen-uitgaven-extramuraal
- volume of AT per category? (optimally longitudinal) – Yes
- expenditure on AT by the statutory health system? – Yes
- out-of-pocket spend (cost-sharing + direct payments)? – No

G) Policy (process)

1) Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

There is a trend of exclusion of certain ATs for mobility and home living: for example, walkers, crutches, special chairs 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) that should be easily affordable by individuals, are not subsidized by the public health care system.

2) Are there any recent/relevant political debates or policy documents/strategies?

Yes, especially regarding the assistive devices provided under the WMO. 32% of Dutch AT users complain 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 (Van Harten & Toersen 2015).
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).

Van Harten C, Toersen W (2015). Rapport meldactie'Hulpmiddelen' Ervaringen met het aanvragen, verkrijgen en gebruiken van hulpmiddelen. Utrecht, NPCF.

New Zealand

A) Regulatory framework *(highlight differences per device type if applicable)*

What is the governing legislation for the coverage of ATs?

There are several pieces of legislation, international conventions, strategies, policies, standards and guidelines which have a cumulative impact on the provision of support and services for those who experience disability. Some of these which have relevance to the regulation and coverage of Assistive Technologies in New Zealand include:

International Conventions:

New Zealand does not have a specific anti-discrimination or disability rights act but instead is guided by the ***United Nations Convention on the Rights of Persons with Disabilities 2006.*** New Zealand ratified the UNCRPD in 2008 which

> *"clarifies the obligations and legal duties of States to respect and ensure the equal enjoyment of all human rights by all persons with disabilities. The Convention identifies areas where adaptations have to be made so that persons with disabilities can exercise their rights and areas where the protection of their rights must be reinforced because those rights have been routinely violated. It also establishes universal minimum standards that should apply to everyone and that provide the basis for a coherent framework for action".* (*https://www.un.org/development/desa/disabilities/resources/handbook-for-parliamentarians-on-the-convention-on-the-rights-of-persons-with-disabilities/chapter-one-overview-4.html accessed 28 May 2018)*

Signatories of the UNCRPD are required to report regularly on compliance with these obligations and legal duties. The New Zealand Government's Disability Strategy 2016 and the Disability Action Plan 2014-2018 seeks to address the implementation of the Convention within New Zealand.

New Zealand Legislation:

- ***Health and Disability Commisioner Regulations 1996 - Code of Health and Disability Services Consumers' Rights*** "established the rights of consumers, and the obligations and duties of providers to comply with the code. It is a regulation under the Health and Disability Commissioners Act". This includes having services that treat people with respect and take into account their needs, respect independence of consumers, ensure the right to effective communication, the right to full information, the right to informed choice and consent, the right to support and the right to complain.

  Source: Health and Disability Rights Commission https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/ (accessed 28 May 2018)

- ***New Zealand Public Health and Disability Act 2000*** introduced a major change to the public funding and provision of personal health services, public health services, and disability

support services in New Zealand. It established new publicly owned health and disability organisations, such as District Health Boards (DHBs) that are responsible for meeting the needs (through direct provision or purchasing services) of their geographically defined population. The Act also introduced primary health organisations (PHOs) that are non-government networks of private for-profit general practitioners/practices that are contracted by the DHBs to provide community-based primary care care and the Pharmaceutical Management Agency (PHARMAC).

Strategies:

- ***The New Zealand Disability Strategy 2001/2016*** - The aim of the New Zealand Disability Strategy: Making a World of Difference – Whakanui Oranga is to eliminate barriers wherever they exist. The barriers range from the purely physical, such as access to facilities, to the attitudinal, due to poor awareness of disability issues

  The Strategy guides Government action to promote a more inclusive society. It is an enduring framework which ensure that government departments and other government agencies consider disabled people before making decisions. It sits alongside other government programmes such as the Positive Ageing Strategy, the New Zealand Health Strategy and the Re-evaluation of Human Rights Protections in New Zealand.

Policies/standards/guidelines:

- Assistive Technology Guidelines, Ministry of Education 2008

There are three level of administration of coverage decision-making:

- Local (service managers)
- District/Regional (DHB, district and regional managers)
- National (Ministry of Health)

This administrative structure is used to identify, assess the best possible solution for person with disability and offering resolution, if solutions are not reached in a bottom up approach (starting from local administration to national). These services occur within the parameters of MOH specifications and the service is focused onenabling and promoting functional independence within the person's own context. The vision is for disabled person to live in their homes and participate in their communities as other New Zealanders do.
Most coverage is funded through the taxation system. Where funding is provided through the Accident Compensation Corporation, this funding is raised through the taxation system and also through levies paid by employers and the vehicle registration system.

Are there human rights/disability/employment laws that influence coverage?

New Zealand does not have a specific anti-discrimination or disability rights act but instead is guided by the *United Nations Convention on the Rights of Persons with Disabilities* 2006 to protect the human rights of disabled people. (See above)

What is the level of administration of coverage decision-making? National/regional/local?

There are three level of administration of coverage decision-making in the core publicly-funded health system:

- Local (service managers)
- District/Regional (District Health Board (DHB), district and regional managers)
- National (Ministry)

This administrative structure is used to identify, assess the best possible solution for person with disability and offering resolution, if solutions are not reached in a bottom up approach (starting from local administration to national). These services occur within the parameters of MOH specifications and the service is focused on enabling and promoting functional independence within the person's own context. The vision is for disabled person to live in their homes and participate in their communities as other New Zealanders do.

Do individual payers have flexibility in coverage decision-making? (distinguish between add-on coverage and general flexibility)

This does not apply as New Zealand is a single-payer at the federal and subnational levels.

What is the role of NGOs? (note: is the role formalized or symptomatic?)

We identified one organisation (Workbridge) that allocated funding for job-seekers who were not eligible for Ministry of Health or ACC funding for ATs. Our review does not cover the role of non-government organisations in funding assistive technologies and devices from money raised from non-public sources. It is difficult to be definitive about the role of NGOs, but New Zealand does not have a strong tradition of well-resourced and independent philanthropy. As such, NGO funding of ATs is likely to be relatively minimal and ad hoc.

Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.)

All public schemes described are funded through taxation. ACC is also funded through employment levies and vehicle registration charges.

B) Devices included

Mobility aids (e.g. wheelchairs, walkers, crutches)?

Types of AT covered by ACC*:* ACC does cover various assistive technologies for people to help with an injury.

- Hearing aids and batteries
- Braille equipment or glasses
- Wheelchairs, walking frames or crutches
- Specialised chairs or furniture
- Voice recognition software

- Artificial limbs.

***Type of AT covered by MOH/MOE**:*

- Communication AT (face to face and written communication)
- Hearing AT
- Vision AT
- Walking and standing
- Wheeled mobility and postural management
- Personal care
- Household management
- Vehicle modifications

Based on the devices people could use them for as long as they need and then return eg. ACC covered wheelchairs, walking frames or crutches can be returned if they are no longer needed or required.

Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

Respiratory aids? (e.g. CPAP machines, oxygen support)

Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices)

C) Requirements for inclusion of devices in benefit catalogue

What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)*

Equipment provided by the Ministry of Health is categorised into three bands, according to specific criteria:

- Band 1
- Band 2
- Band 3

Band 1 - Equipment is equipment which has been selected following a formal tender process. Criteria for selection in Band 1 are that items:

- Meet the needs of a wide range and large number of disabled people, and
- Are low cost (generally less than $1,000 excl. GST), and
- Are durable and the majority are able to be reissued in a cost-effective way.

Equipment is able to be supplied at the lowest possible price, resulting in greater value for money. Many Band 1 Equipment items could be self-purchased in regular retail stores and there is generally a low consequence of risk in relation to its provision.
Not all low cost items are included in Band 1 Equipment. Items that are low cost and rarely

requested but that have not been selected through a tender process are subjected to the Prioritisation Tool. All other items are considered to be in Band 3 (previously known as Complex).

Band 2 - Equipment is equipment which has been selected through formal procurement arrangements. Criteria for selection in Band 2 are that items:

- Do not have high specifications or features and are not complex to use or customised for a person, and
- Generally cost less than $3,000 (excl. GST), and
- Are regularly requested.

Band 3 - Equipment is equipment which has been selected through formal procurement arrangements (including direct purchase for one-off items). Criteria for selection in Band 3 are that items meet one or more of the following:

- Are complex and/or have high specifications or features
- May be customised and individualised
- Are high cost (generally $3,000 or more)
- Are supplied in low volumes, irrespective of their cost
- Require an EMS Assessor to have a higher skill level and experience
- Result in a higher consequence of risk to a person following an inappropriate recommendation by an EMS Assessor.

Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

There is no finite, specific list of what is included. However, the Bands outlined above include lists of what is typically included within these bands.

The two procurement agencies (ENABLE and Accessable) tender for the purchase and supply of some Band 2 and Band 3 Equipment. Applicants are requested to consider these products as the first choice for trial or purchase.

The EMS uses a Prioritisation Tool. This tool is used to prioritise applications for assistance rather than specific pieces of equipment. Therefore, details of the Prioritisation Tool are provided below in the 'Eligibility' section.

(Especially if there is no HTA) **Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?**

Any requirements would be specified through the Ministry of Health's procurement and tendering processes.

How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

Instead of a positive list, products identified through the tendering process are recommended, which means that applicants are able to make a case for products that have not been chosen through the tendering process.

D) Eligibility *(highlight differences per device type if applicable)*

Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

The Ministry of Health evaluates an individual's eligibility for AT through the Equipment and Modification Services (EMS). The purpose of the Ministry of Health funded EMS is to:

- „Support people with disabilities and their families, to live as independently and safely as possible
- Make a significant, consistent and reasonable contribution to enabling people with disabilities to participate (if and when they want to) in activities inside and outside their home and in their local communities". https://www.health.govt.nz/system/files/documents/pages/equipment-manual-nov2014.pdf, p. 8)

Eligibility for AT is assessed by an EMS assessor, who may liaise with a medical professional to obtain further information about the cause and nature of person's disability.

Applications for equipment from Bands 2 and 3 under the following categories must be assessed using the EMS Prioritisation Tool:

- All complex equipment not on the Ministry List (Bands 2 & 3, including refurbished items and equipment to be trialled)
- Accessories and modifications to equipment if likely to cost **more** than $1000 (excluding GST).
- Spectacles requested through Vision Assistive Technology
- Basic housing modifications
- Complex housing modifications
- Vehicle purchase & modifications

Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)*

According to the Ministry of Health of New Zealand's Equipment and Modifications Service: Equipment Manual (2014) eligibility means:

the right to be considered for publicly funded support services. It is neither an entitlement, nor a guarantee, to receive any particular service. To be eligible for consideration of funding towards the provision of equipment the person must:

- *be eligible for publicly funded Health and Disability Services (as set out in the Health and Disability Services Eligibility Direction 2011); and*
- *have a disability as defined by the Ministry; either physical, intellectual, sensory (vision and/or hearing) or a combination of these, or an age-related disability, which is likely to:*

- *remain after the provision of treatment and/or rehabilitation*
- *continue for at least six months, and*
- *impact on their ability to do some everyday tasks, resulting in a need for ongoing support.*

- *The person will generally not be eligible for cover or entitlement for services through Accident Compensation Corporation (ACC) under the Accident Compensation Act 2001.(p X)*

Source: MOH(2014) Equipment and Modifications Service: Equipment Manual. Ministry of Health. Wellington: October 2014 accessed from https://www.health.govt.nz/system/files/documents/pages/equipment-manual-nov2014.pdf, p. 8)

For disability-related needs arising from an accident/injury, the Accident Compensation Corporation has eligibility criteria:

A physical injury is when there is actual damage to your body. This includes:

- sprains or strains - such as ankle, back, knee or shoulder sprains
- wounds - cut, broken or bruised skin
- burns
- fractures
- dislocations
- dental injuries
- hearing loss
- loss of consciousness.

ACC covers most physical injuries if they're caused by:

- an accident
- sexual violence
- a condition that comes on gradually because of work.

ACC can also cover injuries that are long-term, permanent or that happened at birth.

Is there (periodic) reassessment of eligibility required?

Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?
Yes, Ministry of Education has a different eligibility criteria. Ministry of Social Development also funds an NGO (Workbridge) to disburse funding for equipment relevant to job-seeking activities.

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?
Cost sharing can apply to modifications of vehicles and homes.

Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

No

How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

(Don't have this information)

What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

We are unable to answer this.

E) Access pathways

How is access triggered? Does the individual and/or the provider have to apply? To whom?

Access to assistive technology is ultimately gained through an assessment by the Equipment and Modification Service (EMS) conducted by an EMS assessor who is usually trained health professional. Referral to the EMS can be from a family doctor (general practitioner) or a Needs Assessment Service Coordination agency (NASC)

The individual needs are assessed via Equipment and Modification Services (EMS), EMS are one of the many services funded by the Disability Support Services, Ministry of Health to assist people with disabilities and their families to live as independently and safely as possible. EMS assessors hold certain areas of accreditation with in speciality and make recommendation about types of ATs for people with disability. Complex AT assessment may require a referral to a specialist assessment service such as communication AT, wheeled mobility/postural management. Based on the MOH eligibility guidelines and persons condition application is made. Based on the assessment and outcome of the application the devices can be procured.

Who is responsible for procuring and maintaining the device?

<u>Procurement:</u>
There are two organisations that manage contracts for the government to provide and maintain

devices for disabled people: *Accessable* services the Northern part of the North Island while *Enable* provides services for the remainder of the country. Accessable "funds the provision of hearing aids, equipment, housing alterations and vehicle modifications on behalf of the Ministry of Health". The organization also ensures technical support and a repair service is available to customers for the equipment provided.
Source: *http://www.accessable.co.nz/services/our-services (Accessed 28 May 2018)*
Maintenance:
Individuals, whanau (family) and support people are responsible for ongoing maintenance and repair of equipment.
Source: *Ministry of Health (2014) Equipment and Modification Services: Equipment Manual. October 2014. Accessed from https://www.health.govt.nz/system/files/documents/pages/equipment-manual-nov2014.pdf on 28 May 2018.*

Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

Once an EMS advisor has recommended an item of equipment to meet the needs of a disabled person, it is possible for some items to be obtained through one of the equipment providers on loan, to include:

- wheelchairs
- shower stools
- raised toilet seats
- adjustable beds
- walking frames
- hoists
- communication devices (eg, communication boards, equipment that speaks for you, computer software for work or tertiary study)
- visual or vibrating alert systems (eg, smoke alarms)
- magnifiers.

Source: https://www.health.govt.nz/your-health/services-and-support/disability-services/types-disability-support/equipment-and-modifications-disabled-people/equipment-disabled-people

F) Data

Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

There is some expenditure data provided by one of the Equipment and Modifications providers (ENABLE NZ) by District Health Board.

"This is raw financial data about new spend in each District Health Board and does not include costs

for re-issue, repairs and maintenance costs associated with Equipment and Modification Services. It accounts for only those items that have been purchased and paid for in each quarter and does not include any items currently on the waitlist or items that may have been approved but not yet invoiced. Please note that whilst the country is split into District Health Board area, Equipment & Modification Service applications are not solely from District Health Board services."
Source: https://www.disabilityfunding.co.nz/equipment/equipment-and-modification-services-demand-by-district-health-board-area (accessed 28 May 2018)

AOA COST BAND	DESCRIPTION	NATIONAL AVERAGE SPEND
CAT-1	Communication Assistive Technology ($2,000 or less)	$336.02
CAT-2	Communication Assistive Technology ($2,001 or more)	$8,061.00
HAT	Hearing Assistive Technology	$336.72
HOUSING-1	Housing Modifications ($2,000 or less)	$688.49
HOUSING-2	Housing Modifications ($2,001 to $10,000)	$4,954.66
HOUSING-3	Housing Modifications ($10,001 or more)	$11,313.97
PSCHSM-1	Personal Care & Household Management ($500 or less)	$142.75
PSCHSM-2	Personal Care & Household Management ($501 to $5,000)	$1,298.95
PSCHSM-3	Personal Care & Household Management ($5,001 or more)	$7,399.29
VAT	Vision Assistive Technology	$556.52
VEHICLE-1	Vehicle Driving Assessment	$350.00
VEHICLE-2	Vehicle Modification	$6,937.77
VEHICLE-3	Vehicle Purchase	$8,276.60
WLKSTD	Walking & Standing	$544.07
WMPM-1	Wheeled Mobility & Postural Management ($1,000 or less)	$397.77
WMPM-2	Wheeled Mobility & Postural Management ($1,001 to $10,000)	$2,855.91
WMPM-3	Wheeled Mobility & Postural Management ($10,001 or more)	$12,503.70
WMPMLYG	Wheeled Mobility & Postural Management (Lying)	$1,053.85
GRAND TOTAL		$665.50

G) Policy (process)

Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

We don't have information to answer this question

Are there any recent/relevant political debates or policy documents/strategies?

Disability Action Plan 2014-2018 https://www.odi.govt.nz/nz-disability-strategy/disability-action-plan/

Disability Strategy

Norway

A) Regulatory framework *(highlight differences per device type if applicable)*
1) What is the governing legislation for the coverage of ATs? The National Insurance Act [Lov om folketrygd] of 1997. The Act's purpose is to provide financial security by ensuring income and compensating for special expenses due to unemployment, pregnancy and birth, child-rearing, illness and injury, disability, old age and death. Part IV the law discusses benefits available in case of ill health (health services, allowances, funerals, sick pay, benefits for children's and other dependents' disease and benefits to compensate for the expenses for the improvement of working and functioning in daily life). Part IV also provides rules for additional benefits, disability and occupational injury coverage.
2) Are there human rights/disability/employment laws that influence coverage? Chapter 4 of the Working Environment Act [Arbeidsmiljøloven] (2005) states the duties of the employer in facilitating equal access to the workspace for all employees. According to § 4-4, it is the responsibility of the employer to provide ATs (Helsedirektoratet, 2017).
3) What is the level of administration of coverage decision-making? National/regional/local? *From the Commonwealth Fund's Norwegian Health System profile:* In general, parliament determines what is covered, although there is no defined benefit package other than for new and costly treatments and technologies. Primary health and social care is the responsibility of the municipalities, with Norway's ministry of health playing an indirect role through legislation and funding mechanisms. In specialist care, the ministry also plays a direct role through its ownership of hospitals and its provision of directives to the boards of regional health care authorities (RHAs). *https://international.commonwealthfund.org/countries/norway/* Specifically for assistive technologies, a uniform national system was established in 1995 with the aim of ensuring that users are given the same level of services and are met by professionals with the same expertise regardless of their area of residence. 18 regional AT centres (one in each county) compose the referral system. The comprehensive responsibilities of the municipality include individual needs assessment, assisting in application and acquisition, adaptation and adjustment, training, service and repair of assistive devices.
4) Do individual payers have flexibility in coverage decision-making? *(distinguish between add-on coverage and general flexibility)* Not necessarily. In the case of major categories of assistive devices, such as manual and electric wheelchairs, hoists, environment controls etc., the Norwegian Labour and Welfare Service (= the National Health Service, "NAV") enters into procurement framework agreements for the whole country. ATs covered by such framework agreements constitute the "national assortment". Regional AT centres make their own agreements for some of the smaller categories of assistive devices. If the national

assortment does not include any assistive devices that meet the user's needs, an application can be made for reimbursement of additional devices. There must be very good reasons for making such an application and its granting may depend on the decentralized decision-making body. Thus there might be flexibility, albeit by exception.
5) What is the role of NGOs? *(note: is the role formalized or symptomatic?)* Symptomatic (and by all appearances not significant).
6) Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.)) Principally, coverage is ensured for every resident and tax-paying worker in Norway or on the Norwegian continental shelf. *From the Commonwealth Fund's Norwegian Health System profile: Coverage is universal and automatic for all residents. It is financed through national and municipal taxes. Social security contributions finance public retirement funds, sick leave payment, and, for some patient groups, reimbursement of extra health care costs.* *https://international.commonwealthfund.org/countries/norway/*
B) Devices included
1) Mobility aids (e.g. wheelchairs, walkers, crutches)? Yes, see A4
2) Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts) Yes, see A4
3) Respiratory aids? (e.g. CPAP machines, oxygen support) Yes
4) Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones, reading and writing devices) Yes. Reading glasses are only covered upwards of a certain degree of disability. Coverage is broad and budgetary constraints at the level of local authorities do not constitute grounds for refusal of coverage. An example of the type of coverage that can be expected is the following: Since 2014, pupils with reading and writing impediments, and dyslexia, can apply every four years for a computer grant of 3200 NOK.
C) Requirements for inclusion of devices in benefit catalogue
1) What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)* § 10-7 of the National Insurance Act describes an assistive technology as a device [or a measure] that contribute to reduce practical problems in persons with disability. Most ATs are classified as medical

devices and are thus covered by the EU Medical Device Directives (and the succeeding Medical Device Regulation, adopted in 2017), which apply to the EU, European Economic Area (of which Norway is a member) and Switzerland. To be sold on the markets of the EU, European Economic Area or Switzerland, medical devices need to obtain a certificate of conformity to specific rules (Conformité Européene or CE mark) from a notified body. A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. The European Commission publishes a list of such notified bodies. For an example, see TÜV Rheinland (site in english: https://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html)

The new EU regulation on MDs is in effect since May 2017 (Medical Device Regulation 2017/745, MDR). In line with its preceding EU framework for the market approval of MDs (Directives 90/385EEC, 93/42/EEC and 98/79/EC), it mainly addresses the issues of risk and functionality for devices aiming to enter the EU market. Depending on its intended purpose and invasiveness, a MD will be assigned to a risk class; different approval requirements apply depending on class.

2) Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

While HTA is established in Norway, there does not seem to be a lot of activity on ATs.

3) *(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?

Since Norway does not have a clearly defined positive list, this is not fully applicable. Quality criteria do apply in the framework agreements for purchasing ATs (see A4).

4) How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

Not fully applicable, see C3. However, Norway has a horizon scanning process for the identification of emerging technologies which could feed into informing the central Assistive Technology Unit at NAV as well as the AT centres.

D) Eligibility *(highlight differences per device type if applicable)*

1) Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

Individual determination. Persons whose functional capacity is impaired for more than two years (due to illness, injury or physical defects) 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.

In any case, ATs must be necessary and appropriate for improving the person's ability to solve day-to-day practical problems. Eligibility is determined by trained personnel (usually occupational therapists or physiotherapists) at the local authorities, who are responsible for identifying and assessing user needs, recommending and providing assistive devices, as well as following up the users' situation in daily life. They also select the appropriate AT following consultation with the user and file an application with the regional AT centre. (NAV 2017)

2) Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)*

See D1. (No criteria in law, duration plays a role in procurement pathway).

3) Is there (periodic) reassessment of eligibility required?

Depends on the condition, but generally a reassessment would takes place following a new (modifying) application.

4) Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

The Work Environment Act (2005) § 4-4 commits the employer to facilitate universal access and create a supportive work environment for disabled employees.

Pupils or students with special requirements are entitled to individually adapted tuition (Education Act, Chap. 5, Section 5-1). Assistive devices (such as a computer) may be a necessary part of the tuition process. When tuition depends on assistive devices, a teamwork is required between the educational institution and the assistive technology centre. (NAV 2017)

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

1) Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?

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.

Some cost-sharing might apply to certain technology types: Under the national insurance scheme, assistive devices are available for training, stimulation and activation of children and young people under the age of 26. However, assistive devices for activation are also available for persons older then

26 years of age, but a fee of up to 10% of the cost of the assistive device must be paid by the user. In general, Norway has annual caps, set by Parliament, for out-of-pocket expenditure, above which fees are waived. For 2016, the cost-sharing ceiling for most services was approx. USD223. A second ceiling, for services such as physiotherapy and certain dental services, was set at USD272.

2) Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

Not applicable, see D1.

3) How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

This is not an applicable model.

4) What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

See A4.

E) Access pathways

1) How is access triggered? Does the individual and/or the provider have to apply? To whom?

The individual applies for a device from the regional AT center, with optional guidance by the local NAV office. However, the local office is ressponsible for determining eligibility (e.g. by requesting medical proof, see also D1).

2) Who is responsible for procuring and maintaining the device?

The regional AT centres. There are both regular (periodic) and ad hoc follow-up pathways. Examples for the periodic follow-up on the maintenance status of electromedical ATs:

- Powered wheelchairs, every 2nd year
- Lifts, every year
- Hoists, every 2nd. Year
- Beds, every 4th. year

3) Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

In principle, ATs are loaned in the Norwegian system. There is a systematic system on refurbishment of used assistive devices. The devices are properly cleaned, and the worn out parts are replaced before they are reused – this is the responsibility of the regional AT centres. In 2016, on average 29% of ATs provided to users were refurbished.

F) Data

1) Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

There is a national ICT system (Oracle eBusiness Suite) for registration of the costs and distribution of ATs, repairs and follow-up services. Statistics on county and national level are produced every month. In 2015, 134 651 individuals (2,6 % of the population) were lent any sort of AT by one of the 18 assistive technology centres and a total of 420 000 persons were using ATs (Government of Norway 2017a, pp. 43; 51).

G) Policy (process)

1) Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

Since the establishment of the current system in 1995, the trend has been stable.

2) Are there any recent/relevant political debates or policy documents/strategies?

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).

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United Kingdom (England)

A) Regulatory framework *(highlight differences per device type if applicable)*

1) What is the governing legislation for the coverage of ATs?

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.

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. Under the Health Act (2006), the Secretary of State has a legal duty to promote a comprehensive health service that provides care free of charge, apart from services with charges already in place. Rights for those eligible for National Health Service (NHS) care are summarized in the NHS Constitution; they include the right to access to care without discrimination and within certain time limits.

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". 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.

2) Are there human rights/disability/employment laws that influence coverage?

According to the Government's website, the Equality Act 2010 and the United Nations (UN) Convention on disability rights help to enforce, protect and promote the rights of persons with disabilities.

3) What is the level of administration of coverage decision-making? National/regional/local?

(See A1:) The scope of benefits covered by the NHS (at national level) is not a priori set out in legislation. Rather, it provides services "to such extent as [considered] necessary to meet all reasonable requirements". 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 ("The NHS Constitution").

4) Do individual payers have flexibility in coverage decision-making? *(distinguish between add-on coverage and general flexibility)*

The precise scope of the NHS is not defined in statute or by legislation, and there is no absolute right for patients to receive a particular treatment. However, the statutory duty of the Secretary for Health is to ensure comprehensive coverage.
From the Commonwealth Fund health system profile on England: The volume and scope of covered services are generally a matter for local decision-making, but the NHS Constitution also states that patients have a right to drugs or treatment approved in technology appraisals carried out by the

National Institute of Health and Clinical Excellence (NICE), if recommended by their clinician. For drugs or treatments that have not been appraised by NICE, the NHS Constitution states that NHS Clinical commissioning groups (CCGs), which commission local health services, shall make rational, evidence-based decisions.
https://international.commonwealthfund.org/countries/england/
(Note: ATs are not frequently subject of NICE evaluations).

5) What is the role of NGOs? *(note: is the role formalized or symptomatic?)*

NGOs are key players in providing consolation services to patients in need of ATs.Tellingly, the NHS Choices website clearly points users in the direction of charity support (for two examples, see Annex 4 of the synthesis report for Europe).

6) Reflect on nature of coverage (mandatory insurance? Automatically through taxes? For whom (residents/citizens etc.))

From the Commonwealth Fund health system profile on England: Coverage is universal. All those "ordinarily resident" in England are automatically entitled to NHS care, largely free at the point of use, as are nonresidents with a European Health Insurance Card. For other people, such as non-European visitors or undocumented immigrants, only treatment in an emergency department and for certain infectious diseases is free. The majority of funding for the NHS comes from general taxation, and a smaller proportion from national insurance (a payroll tax). The NHS also receives income from copayments, people using NHS services as private patients, and some other minor sources.
https://international.commonwealthfund.org/countries/england/

B) Devices included

1) Mobility aids (e.g. wheelchairs, walkers, crutches)?

Provided by NHS (coverage may be tied to certain conditions or apply only to certain device types and models). For example, 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.

2) Household aids? (e.g. hospital beds, stair lifts, bathroom devices, transfer lifts)

Provided by local councils (coverage may be tied to certain conditions or apply only to certain device types and models)

3) Respiratory aids? (e.g. CPAP machines, oxygen support)

Provided by NHS (coverage may be tied to certain conditions or apply only to certain device types and models)

4) Audio, Visual and Communication aids? (e.g. bone anchored hearing aids, adaptive telephones,

reading and writing devices)

Provided by NHS (coverage may be tied to certain conditions or apply only to certain device types and models)
E.g.: 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.

C) Requirements for inclusion of devices in benefit catalogue

1) What are the requirements for marketing approval of assistive devices? *(highlight differences per device type if applicable)*

Most ATs are classified as medical devices and are thus covered by the Medical Device Directives (and the succeeding Medical Device Regulation, adopted in 2017; see next paragraph for more detail). To be sold on the markets of the EU, European Economic Area or Switzerland, medical devices need to obtain a certificate of conformity to specific rules (Conformité Européene or CE mark) from a notified body. A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. The European Commission publishes a list of such notified bodies.
For an example, see TÜV Rheinland (site in english:
https://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html)

The new EU regulation on MDs is in effect since May 2017 (Medical Device Regulation 2017/745, MDR). In line with its preceding EU framework for the market approval of MDs (Directives 90/385EEC, 93/42/EEC and 98/79/EC), it mainly addresses the issues of risk and functionality for devices aiming to enter the EU market. Depending on its intended purpose and invasiveness, a MD will be assigned to a risk class; different approval requirements apply depending on class.

It is as yet unclear what Brexit will mean for the regulation of health technologies (currently dependent on the EU regulatory framework).

2) Health technology assessment: Is there an evaluation of effectiveness/safety/cost-effectiveness/budget impact/other elements (e.g. social/legal/organizational elements) before devices enter the positive list?

See also A1 and A4: The scope of benefits covered by the NHS is not a priori set out in legislation. However, the NHS Constitution also states that patients have a right to drugs or treatment approved in technology appraisals carried out by the National Institute of Health and Clinical Excellence (NICE), if recommended by their clinician. ATs are not frequently assessed by NICE (see also Annex of the synthesis report for Europe).

3) *(Especially if there is no HTA)* Are there any additional specifications/requirements (e.g. regarding product quality) for products to be included in the positive list?
Not clearly defined (as benefit package not explicit).

4) How are devices included in the positive list? (e.g. at the request of the manufacturer, other identification mechanism)

See C3.

D) Eligibility *(highlight differences per device type if applicable)*

1) Is eligibility determined at the individual level? Who is responsible for that determination (individual providers/specific centers etc.)? Do/can payers pull in additional external expertise (where from?)?

Eligibility is determined by local authorities at community level, with each local authority having different criteria – those who do not meet them have to purchase AT privately (potentially with NGO assistance).

Whether an AT will be provided by the NHS or through council funding depends on 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.

2)* Are there clearly defined criteria for eligibility (in law/regulation) and at which level? Do age/income/disease/long-term* nature of condition and need factor in? *(for duration of need: does the way the device is obtained differ for transitory vs. permanent ailments?)

Under the Equality Act 2010, a person has a disability if they have a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on their ability to do normal daily activities. "Substantial" is more than minor or trivial, for instance it takes much longer than it usually would to complete a daily task like getting dressed. "Long-term" means 12 months or more. There are special rules about recurring or fluctuating conditions, eg arthritis.

Means testing applies in the context of locally determined eligibility for relevant social care services provided at the community level.

3) Is there (periodic) reassessment of eligibility required?

Depends on the condition and the AT provision pathway. The needs of and provided support for individuals eligible for NHS continuing healthcare (see D1) are reviewed at least annually after the initial assessment, among others to determine continued eligibility.

4) Are there significant provisions and pathways of determining eligibility in the context of employment and/or education?

Education: Section 25 of the Children and Families Act 2014 places a duty on local authorities that should ensure integration between educational provision and training provision, health and social care provision, where this would promote wellbeing and improve the quality of provision for disabled young people. The Care Act of 2014 stipulates that local authorities and NHS clinical commissioning groups must make joint commissioning arrangements for education, health and care provision for children and young people with disabilities, including services such as specialist support and therapies, speech and language therapy, assistive technology and personal care (or access to it).

Employment: Under the Equality Act 2010, employers have a duty to make reasonable changes to the facilities for disabled employees known as 'reasonable adjustments'. These adjustments aim to avoid an individual being put at a disadvantage compared to non-disabled people. This pertains to ATs such as ramps and lifts, but not to ATs that would be issued for personal use.

D) Pricing, cost-sharing and procurement *(highlight differences per device type if applicable)*

1) Is there cost-sharing for assistive devices? Does it depend on the type of technology? Linking to D2, is there income-related variation in cost-sharing obligations (including government taking over fully for indigent/unemployed)? Are there any other protection mechanisms (out-of-pocket payment caps etc.)?

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).

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 toiled seats and a small range of sensory communication equipment are included in the national catalogue. 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).

Under the traditional provision route, home equipment is 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. Only certain types of hearing aids are available on the NHS: more advanced models need to be purchased privately.

2) Beyond direct cost-sharing modalities (co-insurance, co-pays, deductibles), are there tax credits for partially or not covered devices?

No tax deductions.

3) How (and how often) are device prices determined? Do patients have to pay the difference between tariff price and actual price if they choose a more expensive device for the same need?

See D1 – voucher scheme for certain ATs such as wheelchairs enables wider choice and requires covering the difference if patients opt for more expensive models. Tariff catalogue for the relatively new "retail model" of AT provision lists prices (tempo of revision unclear) but with flexibility for local schemes. There is disparity in price for the same product across the UK.

4) What types of contracts are in place for the procurement of assistive devices? Who are the partners, what is their duration and how are they initiated (e.g. tendering)?

The arrangement depends on the type of AT. Both in relation to NHS procurement and in the case of local authorities, there are a number of modalities ranging from individual service/one-off purchases (such as in the case of sophisticated seating for a disabled child) versus tenders which aim to aggregate volume and restrict to just a small number of suppliers and delivery points.

According to the British Healthcare Trades Association (BHTA):

"There is a plethora of differences in the supply chain/procurement route. Methods vary across local authorities (social services and housing), regional local authorities, NHS Trusts, CCGs, regional NHS, external bodies, education and access to work. Then there is also variation in where the equipment is actually to be provided - in hospital, in clinics, in a retail setting, in residential care or the person's (patient's/client's) own home.

Framework agreements, tenders (based on geographical location or on volume), preferred suppliers (providing quotes for equipment as part of the team working alongside assessors who are state registered healthcare professionals, or assessors who are themselves appointed by contract), prescriptions (issued to contractors by GPs or to retailers via community equipment services) - all make for a system that is confusing for purchasers, providers, and public alike."

E) Access pathways

1) How is access triggered? Does the individual and/or the provider have to apply? To whom?

Depends on the level of provision and the type of technology. For NHS-provided ATs, a referral from an NHS professional is needed as an entry point to an assessment by the relevant NHS service – this generally follows the gatekeeping approach of the NHS, whereby the general practitioner (GP) is the patient's point of entry to the health system (in the case of ATs, the GP would refer the patient to the relevant specialist or service). Here an example for wheelchairs:

"*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*."

And the corresponding process for household aids**:**

"If you think you need some adaptations to your home, contact the adult social services department of your local authority, your GP or local Clinical Commissioning Group (CCG), and ask for an assessment by an occupational therapist (OT). The assessment is free.
An occupational therapist will visit you at home and assess your needs. Based on the assessment and what you tell them, the OT will recommend equipment and adaptations to make your life easier. You may also be able to get help with costs."

Under the "retail model" (see D1 for details), prescription is issued by the relevant health professional.

2) Who is responsible for procuring and maintaining the device?

Depends on AT type and model of provision (see D1 & E1). For example, for hearing aids, if the patient opts for an NHS hearing aid provider, the hearing aids will be provided for free as a long-term loan procured directly by the service (and will be maintained by the service, including battery provision). Maintenance for a wide range of ATs used in the community setting is carried out by the contractors/suppliers of the products (see Medequip for one of the largest contractors operating in the UK).

3) Which devices are "loaned" and which are the property of the individual? Are loaned devices refurbished? If so, is there data on savings from this process?

This also depends on the type of device. ATs provided by the NHS are essentially loaned (they are property of the NHS). Under the retail scheme described in D1, patients own their ATs – but, as pointed out above, the scheme does not include all types of devices: 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.

No overall data on refurbishment is available, as this is carried out by individual contractors. But as NHS-provided ATs are on loan, efforts are invested in recyclilng. Medequip (See E2) reports the following: "In 2016, we recycled more equipment than we purchased (£70m recycled vs £55m purchased). Medequip

endeavour to recycle or reuse our full product range, always taking into consideration the life span and condition of equipment and whether or not it is economically viable or appropriate to recycle certain items (e.g. single use items such as the male urinal), ensuring cost efficiencies are met."

F) Data

1) Are there reliable data on:
- volume of AT per category? (optimally longitudinal)
- expenditure on AT by the statutory health system?
- out-of-pocket spend (cost-sharing + direct payments)?

This is generally difficult due to the complexity of the system as described under D4. More comprehensive research would be required to have a clear overview.

G) Policy (process)

1) Is there a discernible trend in levels of eligibility, included devices and/or financial coverage of assistive devices?

Not particularly. The attempt at a retail model followed general policy reform notions in the NHS in the context of the 2000 NHS Plan: its publication marked a significant step in increasing the role of choice and competition in the provision of NHS-funded services. Over the course of the 2000s patients were given more opportunities to choose providers. Recent discussions on the end of the purchaser-provider split in the context of moving towards accountable care organizations may have an impact on AT policy as well in the future.

2) Are there any recent/relevant political debates or policy documents/strategies?

The most recent discussion on this is the potential of capitalizing on AT to close the employment towards contributing to the UK's productivity lag. In a report published in April 2018 the Work and Pensions Committee supported mainstreaming AT and urging the Department of Work and Pensions to allow Personal Independence Payments to be used to lease or buy AT. The relevant report can be found here.

A brief overview of recommendations can be seen https://www.parliament.uk/business/committees/committees-a-z/commons-select/work-and-pensions-committee/news-parliament-2017/report-assistive-technology-17-19/.

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.

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