

RETHINKINGMS IN ITALY

A policy brief



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About RETHINKING MS

RETHINKING MS is a research-driven project which offers tangible policy changes to improve the lives of people living with MS across Europe, building on the 2017 Value of Treatment report from the European Brain Council. The RETHINKING MS series includes RETHINKING MS in Europe – a policy report providing an analysis of unmet MS care and support needs across Europe, and practical and sustainable policy recommendations – and a series of reports providing an in-depth analysis of policy, care and support available for people with MS in Denmark, Italy, Romania and Spain.

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About the European Brain Council

The European Brain Council (EBC) is a non-profit organisation that aims to improve the lives of those living with brain disorders by advancing the understanding of the healthy and diseased brain through bringing together science and society.

About The Health Policy Partnership

The Health Policy Partnership (HPP) is an independent research consultancy, working with partners across the health spectrum to drive the policy and system changes that will improve people's health.

For more information on RETHINKING MS, please visit:

www.braincouncil.eu/RethinkingMS



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Multiple sclerosis (MS) is a complex and progressive disease of the central nervous system, where the immune system destroys brain, optic nerve and spinal cord tissue.¹⁻³

What is happening in Italy?

There are approximately 122,000 people living with MS in Italy ⁴
Prevalence of MS ranges from 198–370 per 100,000 ⁴
Average age at diagnosis is 34 ⁵
Approximately 70% of the MS population are women ⁶

What are the costs of MS in Italy?^{5 6*}

	Mild	Moderate	Severe
Direct costs for healthcare (€)	20,132	23,611	15,670
Direct costs for services and informal care (€)	1,044	6,994	19,575
Indirect costs for short- and long-term absence from work and early retirement (€)	1,717	9,542	18,045
Combined direct and indirect costs (€)	22,900	40,100	53,300

*Average costs per person, per year. Data were collected in 2015. Combined costs are rounded to the nearest €100. The Expanded Disability Status Scale (EDSS) classes MS severity with a score of 0–9: a score of 0–3 is mild, 4–6.5 is moderate and 7–9 is severe. For information on the different types of MS, see the appendix.

WHAT IS MISSING FROM MS CARE IN ITALY?

To better understand unmet needs in Italy, interviews were conducted with experts in MS and an interdisciplinary round table was organised. In order to improve MS care, experts recommended that Italian policymakers and decision-makers should look to ensure:

- access to specialist MS rehabilitation personalised to each individual
- case management, care and support for people with progressive MS
- integrated health and social care pathways for all people with MS, and include MS in the National Plan for Chronicity.





COUNTRY CONTEXT

Despite the far-reaching impact of economic crises, Italy's decentralised healthcare system is considered effective and life expectancy is among the highest in Europe.⁷

The 2008 and 2011 economic crises catalysed a series of cost-containment measures which reduced the overall public expenditure for health.⁷ However, the Italian healthcare system continued to perform well and population health generally continued to improve.⁸ Recent years have seen many governance reforms and adjustments aiming to address regional disparities in access to health and social care.⁷

The National Health System is publicly funded, but out-of-pocket spending can be high. Healthcare spending accounts for 8.8% of GDP, which is equal to the Organisation for Economic Co-operation and Development (OECD) average.⁹ Most services are free at the point of use and therapies that are considered to be cost effective and 'essential' or 'life-saving' are fully reimbursed.¹⁰ However, other therapies are paid for entirely out-of-pocket and, as a result, individual spending on pharmaceuticals is high. A number of payment exemptions exist, including for people with disabilities.⁷

The social and economic differences between regions underpin substantial inequalities in access to and quality of care.⁷ Health and social care is organised at the regional level and provided at the sub-regional level by each local health authority. Geographical inequalities in funding and distribution of resources mean that, typically, the wealthier northern regions provide higher-quality care than the southern regions.¹⁰ This divide is reflected in the movement of people from southern to northern regions for treatment, particularly complex surgery and outpatient care.^{7 11}

National goals include improving equity of funding and increasing the quality and consistency of healthcare.⁷ National performance measures are being utilised to improve quality of care and increase accountability between regions, and new systems are being developed to improve equity in health spending.⁷ Regional initiatives to clarify standards of services include the development of pathways for diagnosis, treatment and support (Percorsi Diagnostici, Terapeutici e Assistenziali or PDTAs); such regional efforts are important steps to achieve national goals.¹²

Responding to the increasing demand for long-term health and social care is a major challenge. Inequalities and capacity issues persist in health and social care.¹⁰ The burden of long-term care is often left to the families of people with chronic conditions, who may provide care directly or pay out-of-pocket for carers of variable quality and training.⁷ Efforts are underway to address shortcomings in the supply of formal care and to regulate the roles of paid carers.⁷ These changes will better support the growing number of people with high or complex healthcare needs.⁷

Efforts to improve integration of primary care into long-term disease management have been variable. It is essential to enhance the role of primary care and general practitioners (GPs) to effectively respond to the increasing demand for long-term care in Italy.⁷ Reforms and innovations have tried to involve GPs more directly in chronic disease programmes such as for diabetes, heart failure and respiratory diseases. Such programmes provide high-quality and effective care, but the actual involvement of primary care can be variable.⁷





MS POLICY LANDSCAPE

The prevalence of MS is increasing in Italy due to rising annual incidence and low mortality rates.⁴ Technological and medical advancements have improved the lives of people with MS, especially for people with a new diagnosis. Achieving equal access to appropriate treatments for the growing population with MS is a major challenge that the Italian system seems committed to tackling.^{4 13}

The National Plan for Chronicity clarifies ambitions to provide person-centred and multidisciplinary approaches for all people with chronic diseases.¹⁴ While the plan does not specifically refer to MS, it is still considered helpful in driving improvements in MS care. The plan emphasises the potential of PDTAs to deliver comprehensive care for chronic conditions such as MS and, as of October 2019, 13 of 20 regions have launched PDTAs for MS.¹⁵

Developing a comprehensive national MS registry is a major objective of the Italian Multiple Sclerosis Society (AISM) and Italian Foundation for Multiple Sclerosis (FISM).^{4 16 17} A nationwide registry in Italy is central to promoting MS research, understanding epidemiology, monitoring drug safety and supporting advocacy and evidence-based policy development.¹⁷ Since 2015, AISM has collected data from 140 MS centres and more than 50,000 people with MS, accounting for 60% of MS centres and 42% of the MS population.¹³ AISM aims to obtain formal recognition of the registry from the national health governing bodies and connect health service data with the clinical records from MS centres for the entire Italian MS population.¹⁶

In addition to its policy efforts, AISM has raised public awareness of MS. AISM takes a leading role in awareness-raising and fundraising. In a 2018 survey conducted by AISM, 97% of respondents reported that they knew what MS was.¹⁶

What policies exist for MS in Italy?

Inclusion of MS in the national non-communicable disease or chronic disease plan	No
Neurological disorders plan	No
Inclusion of MS in neurological disorders plan	N/A
National strategy on MS	No
National clinical guidelines	PDTAs are regionally specific guidelines for health and social care that incorporate recommendations from AISM and guidelines from the Italian Neurological Society and European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). National Reference Guidelines for PDTAs are currently under discussion among AISM, Italian Neurological Society and Ministry of Health
National MS registry	A national Italian MS Register has been established by FISM and AISM in conjunction with Bari University and MS centres, which is expanding data collection. There is also a regional register in Tuscany, ¹⁸ which was the first officially recognised Italian MS register ¹⁶



ORGANISATION OF CARE

‘We want to develop a network of MS clinical centres that will be recognised as an official disease network in Italy. This brings with it dedicated resources and enhanced planning and more autonomy, improving their ability to provide interdisciplinary, responsive and personalised care for people with MS.’

Paolo Bandiera, Italian Multiple Sclerosis Association (AISM)

MS centres are recognised as the key component of MS care in Italy. There are approximately 240 MS centres of varying size, often located within neurology departments in public hospitals.⁴ Around 87% of people with MS receive care in MS centres,¹⁶ which provide planned and emergency neurology appointments, disease-modifying therapies (DMTs) and symptomatic therapies. Most care for people with MS is provided as outpatient or day cases, although overnight admissions may occur in certain cases such as relapses or complications in people with high levels of disability.¹⁹

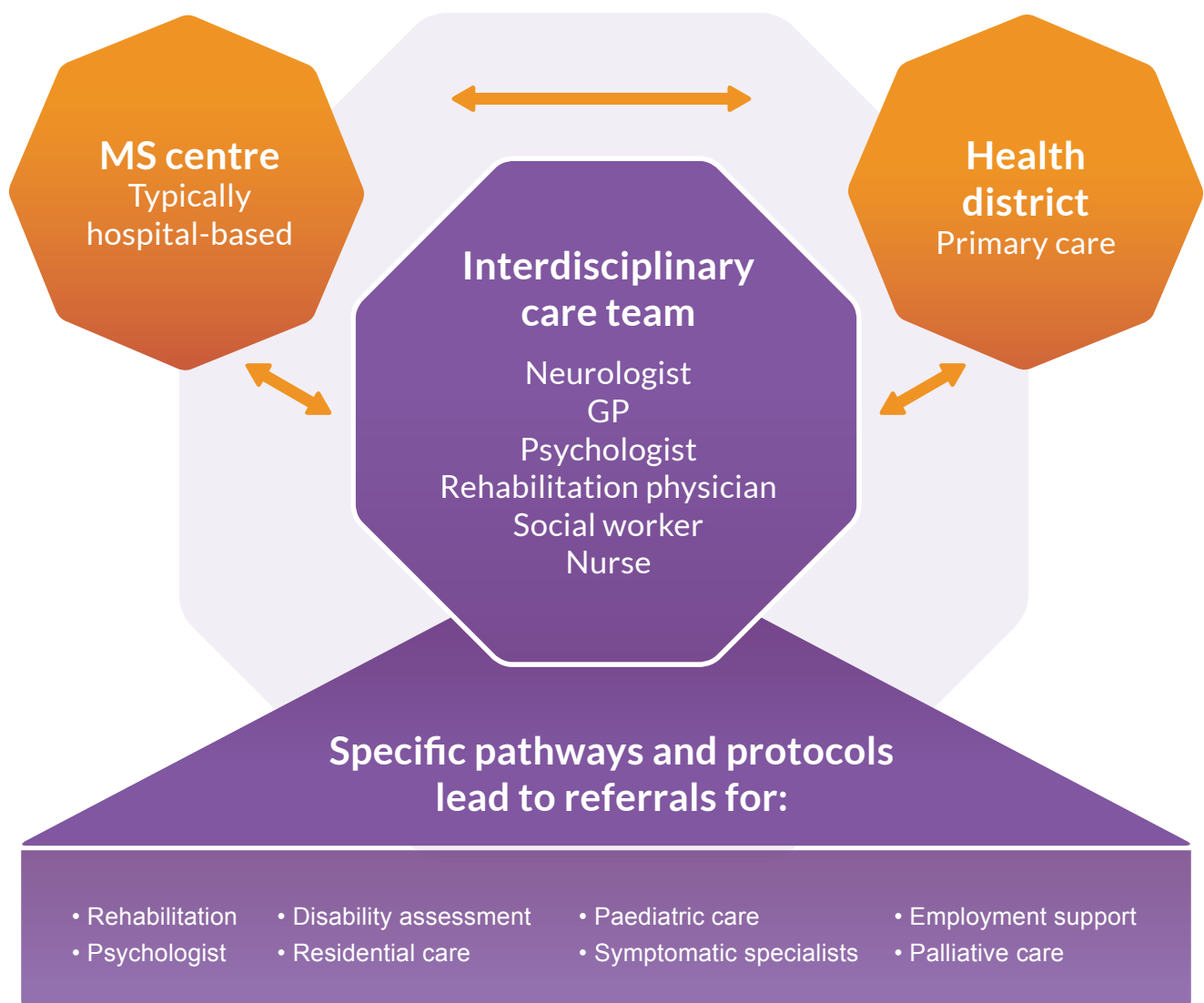
Neurologists typically lead all aspects of care, drawing on the expertise of other specialists from the interdisciplinary team as necessary.⁴ The composition of the interdisciplinary team can vary depending on which centre the person with MS attends for their care.

Geographical inequalities in access to MS rehabilitation are significant. Rehabilitation is an essential component of MS management, supporting people to maintain functionality and quality of life.²⁰⁻²² In Italy, rehabilitation is provided by a network of public and private providers; however, availability of and access to services is unequal across the country.¹⁰ Supply of care is generally inadequate – for example, shortcomings in budgets or local availability of providers means that many people pay out of pocket for all or a significant portion of their rehabilitation.²³ Furthermore, rehabilitation generally focuses on the needs of post-acute patients rather than people with chronic conditions such as MS.¹⁰

The need to improve the linkage between hospital, primary and community care is recognised as a major national challenge. The ideal case management model (*Figure 1*) outlines ambitions for interdisciplinary and integrated health and social care for all people with MS in Italy. However, achieving such a model at scale requires integration and a resource-intensive transformation, particularly in social care.²⁴ Such barriers are significant, and underpinned by historical underfunding and lower prioritisation of social care.²⁵

The transition from relapsing and remitting MS to progressive MS requires a smooth handover from the MS centre to the community. People with progressive MS should increasingly receive care through primary, community and social care teams rather than the MS centre.²⁶ This usually means care is led by a community neurologist with less direct input from specialist MS neurologists.²⁶ However, this is not always the case, and many people are at risk of being lost to follow-up during the transition from specialist to community care.¹⁸ As a result, many people with progressive MS and high levels of disability are predominantly cared for by their families.^{4 6}

Figure 1. Ideal case management model for MS in Italy²⁶



Timely diagnosis and personalised treatment

‘In the past 20 years we have seen a lot of changes and improvements in the care of MS, starting with a timely diagnosis. People receive their diagnosis of MS much earlier than ever before, meaning treatment starts earlier too.’

Professor Maura Pugliatti, University of Ferrara

The diagnostic pathway in Italy is relatively smooth and consistent, despite regional disparities in healthcare. Diagnosis is led by a specialist neurologist at the MS centre, usually on an outpatient basis. The large number of MS centres contribute to the relatively straightforward diagnostic process.¹⁸ Italy has one of the highest levels of magnetic resonance imaging (MRI) machines per 100,000 people among OECD countries,²⁷ further supporting timely diagnosis. Surveys suggest that the interval between first symptoms and diagnosis of MS is shorter in Italy than in other European countries.⁵

People with MS need psychological support from the point of diagnosis, but access can be extremely variable. A diagnosis of MS can be life-changing and psychological support can be extremely helpful to enable people to adjust their lives to MS. Many people with MS experience depression and anxiety⁶ and, particularly for younger people, it can be difficult to accept the diagnosis.²⁸ Guidelines for appropriate communication of diagnosis and psychological support are included in PDTAs, but sustained provision of psychological support is variable.^{16 29} Satisfaction with the level of psychological support people with MS receive increased from 65% in 2013 to 75% in 2017; however, a quarter of people with MS still feel that this area of care should be further improved.⁴

Pharmacological management of MS

‘Too many people with MS must pay for symptomatic therapies due to issues with reimbursement. Therefore, we are working to get a special reimbursement regime for therapies that target MS-specific symptoms such as fatigue.’

Paolo Bandiera, AISM

Access to DMTs can be delayed by regional delays in approval. Overall, approximately 50% of people with MS are on DMTs,⁴ which are prescribed in the MS centre based on decisions between the neurologist, healthcare team and the person with MS.²⁶ All MS centres should be able to provide all DMTs authorised by the Italian Pharmaceutical Agency (AIFA). However, smaller MS centres in some regions may only be authorised to prescribe first-line DMTs, and regional delays exist in implementing AIFA’s decisions on new therapies.¹⁸ Such barriers to access mean that people may travel to other MS centres or regions for treatment.

Cost-containment strategies also restrict DMT access. The increase in prevalence and incidence of MS, alongside the increase in treatments, will result in a rise in public expenditure for MS.^{16 30} The national decrease in overall health expenditure and the increasing expenses of chronic disease therapies, including those for MS, have catalysed cost-containment strategies at the national and regional level.¹⁶ One such example for MS is waiting times for second-line treatment.¹⁶

Some experts have expressed concerns about the AIFA pressures regarding the interchangeability of biosimilar therapies.¹³ AIFA considers professional judgement a key criterion when choosing therapies, but also requires healthcare professionals to consider the economic impact of their therapeutic choices.³¹ This stance, in addition to local performance management or tendered purchasing, risks prioritising budget over therapeutic continuity.¹⁸

Most symptomatic therapies involve out-of-pocket payments, limiting access based on the person’s ability to pay. Many symptomatic therapies are not covered under the national healthcare system, including therapies for fatigue and bowel symptoms.⁴ Such symptoms, if left unmanaged, can have a dramatic impact the person’s ability to fully participate in social or working life.⁴ In one AISM survey, 38% of respondents did not receive all their symptomatic therapies for free, 41% of whom faced a significant negative impact to their household budget because of this out-of-pocket expenditure.^{4 16}

What pharmacological treatments are available in Italy?

Availability of symptomatic therapies	Several symptomatic therapies are not reimbursed; on average, each person with MS pays between €1,325 and €6,500 per year for symptomatic therapies ^{4 16}
Availability of DMTs	All approved by EU ³²
DMT reimbursement	100% reimbursement ³³

Interdisciplinary management of MS

‘We need individual rehabilitation plans for each person with MS. PDTAs should formally establish how rehabilitation needs to be done, who is part of the team and how rehabilitation shall be integrated with other interventions.’

Professor Mario Alberto Battaglia, AISM and Italian Multiple Sclerosis Foundation (FISM), University of Siena

Despite variable numbers of specialist neurologists and nurses in each MS centre, waiting times for appointments across Italy remain acceptable. Understaffing and capacity is an issue both for MS neurologists and MS nurses. In 2019, each full-time MS specialist neurologist follows 150–1,000 people with MS, and each full-time MS nurse follows 220–1,045 people with MS.⁴ Fortunately, capacity does not seem to affect the majority appointments in MS centres:

- For a first appointment, 71% of MS centres have a waiting time of up to two weeks, 24% up to one month and 5% over one month.⁴
- For emergency appointments, 75% of MS centres provided an appointment within 24 hours and 25% within one week.⁴

The ability to coordinate interdisciplinary care in each MS centre depends on the capacity and quality of the local health and social care system. Every MS centre is responsible for ensuring interdisciplinary care. More than 90% formally involve a wide variety of interdisciplinary professionals such as neuroradiologists or opticians, and more than 80% involve psychologists, urologists, rehabilitation physicians or gynaecologists.⁴ However, other professionals are not as regularly involved – for example, only 52% of centres involve social workers and just 14% do so through formal agreements.⁴ Such limited engagement highlights the need to better integrate health and social care.

Most people with MS do not receive personalised rehabilitation, and the types of rehabilitation provided vary significantly. Many people with MS receive general physiotherapy as the main component of their rehabilitation. More specialised approaches are far less common; for example, of all people with MS in Italy, 18% received therapy for sphincter symptoms, 12% for cognitive and speaking symptoms, and only 10% received occupational therapy.⁴ A survey of people with MS showed that only 30% felt that their MS centre provided an appropriate response to their rehabilitation needs, and 31% indicated that rehabilitation services needed improvement.⁴

Rehabilitation services vary based on the availability of facilities in the community and the approach from neurologists. Access to general rehabilitation differs across the country,¹⁰ and these issues are amplified in access to specialist MS rehabilitation services.¹⁸

There are various drivers of limited access to rehabilitation:

- **Financial factors:** MS rehabilitation must be highly personalised to each individual. However, in Italy, rehabilitation is funded in 'packages' of generic physiotherapy, which does not provide incentives for personalised rehabilitation.¹⁸
- **Inpatient or outpatient prioritisation:** inpatient rehabilitation is not appropriate for every person with MS, but in some areas it is the only option available.¹⁸ Conversely, in other areas, only outpatient approaches are available.
- **Cultural and professional factors:** traditional rehabilitation focuses on post-acute conditions and recovery; however, MS rehabilitation aims to maintain function and adapt to changing symptoms. As such, rehabilitation is also dependent on the ability of healthcare professionals and care providers to personalise their approaches.¹⁸

Psychological support plays a key role in MS care, yet only a quarter of MS centres can directly provide such support.¹⁶ A 2017 survey found that 66% of respondents felt they had unmet needs with regard to psychological support,²³ and a 2018 survey found that just over half (52%) of people with MS said that the psychological impact of MS is the biggest challenge they face.¹⁶ Despite these unmet needs, approximately one third of accessed psychological support is provided privately,²³ restricting use to those who can afford it.

How many specialist interdisciplinary services are available in Italy for MS?

Number of interdisciplinary MS clinics	Approximately 240 MS clinics ⁴
Number of specialist rehabilitation services	Approximately 10–15 services specialise in MS rehabilitation ¹⁸
Number of neurologists and MS specialist neurologists	8,000 neurologists ³⁴ Approximately 600 MS specialist neurologists ¹³
Number of specialist nurses	400–500 nurses have received training by the MS Nursing Society (SISM) and FISM, and each year 100 are trained ¹³

Monitoring and long-term follow-up

‘Real innovation in MS management would be improving care transitions from home to the hospital and vice versa. It is essential to have the hospital and the community talking to one another.’

Professor Maura Pugliatti, University of Ferrara

There is significant variability in follow-up depending on the type of MS and use of DMTs. In Italy, 87% of people with MS attend an MS centre: 52% at least once every three months and 29% at least twice a year.⁴ However, frequency of attendance greatly depends on age and level of disability: 68% of younger people with MS – the majority on DMTs – attend an MS centre at least once every three months, more frequently than older people with MS.⁴

For people with progressive MS who are not on DMTs, or those with a high level of disability, follow-up at MS centres can be far less frequent. Among those with high EDSS scores, 35% attend an appointment at the MS centres at least twice a year, which is less frequent than people with lower levels of disability.⁴ People with progressive MS are generally seen in primary care rather than at MS centres, but are at risk of ‘falling through the gaps’ in care and being lost to follow-up if there is no smooth shift of responsibility from the MS centres to the community.¹⁸

Following international guideline recommendations,^{2 35} access to MRIs for ongoing monitoring is good in Italy. In an AISM survey, 36% of people with MS reported having received a brain MRI and 26% a spinal MRI in the last three months.¹⁶ Inclusion of monitoring in PDTA legislation is seen as an important step in ensuring MRI access; compliance with international recommendations for MRI monitoring has been incorporated in two PDTAs and is recommended in other PDTAs.¹⁸



Adaptable support in daily life

‘We are working to overcome a purely medical approach to disability. There was very low understanding of MS, resulting in a systematic underestimation of the invisible symptoms like fatigue. Assessments have got better, but there are still improvements to be made.’

Paolo Bandiera, AISM

Disability assessments to access benefits and support do not always reflect the reality of living with MS. Support available to people with MS from the Italian social protection system includes:

- support to find and maintain employment or work part-time
- financial benefits to compensate for reduced or lost employment and pay for long-term care
- tax discounts, such as tax relief on motor vehicle and home adaptations.

Such protections are provided by organisations at the national, regional and local levels. To apply for benefits, people with MS have their level of disability assessed by a medical committee. However, many committees consider mobility limitations alone, neglecting invisible but common symptoms of MS such as fatigue and pain.¹⁸

Despite legislative protections for people with MS and disabilities in Italy, employment is still a challenge. Legislation exists to ensure that a minimum proportion of employees with a disability are employed in public and private companies, and that employees with a disability (and their carers) are able to adjust their working hours.^{4 36 37} MS-specific legislation also exists to facilitate temporary part-time working arrangements.^{38 39} However, finding and maintaining employment remains difficult for people with MS in Italy. For example, 15% of all people with MS would like to receive more support in finding a job, and this rises to 37% among those aged under 35.¹⁶

Employers are required to make reasonable adaptations to accommodate employees with disability, but there is no public funding to support such adaptations.⁴ As a result, adaptations are frequently made only when there is minimal or no financial burden on the employer. To support workplace adaptations, patient associations such as AISM provide advice, funding, equipment and other services.⁴⁰

Deficits in social care mean informal carers play a significant role in the lives of people with MS. Some people with MS and their families receive financial support from local authorities to pay for care, but the majority of care is often left to the family. For people with severe disability, day-to-day care is one of the most significant costs of MS.^{4 6} One survey found that home care is the service that most people with MS believe needs to be improved.⁴

AIMS and FISM play a significant supportive role in the lives of people with MS, leading national and regional research and advocacy. AISM provides direct support to people with MS and their families via local branches, in the form of information, guidance, legal advice and other services. It also provides specialised rehabilitation services in five MS centres and social care in three centres, which is contracted by public social care commissioners.^{41 42} At the national level, AISM and FISM form a strong advocacy force, running public awareness and fundraising campaigns. FISM funds basic clinical and public health research into MS,⁴³ and AISM has been instrumental in driving legislative employment changes and leading other work to better support people with MS in the community.

What patient groups exist in Italy?

National patient groups	Associazione Italiana Sclerosi Multipla (AISM) www.aism.it
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Case study 1

Developing clear care pathways outlining expected services^{4 14 18}

The National Plan for Chronicity emphasised the goal of developing of integrated health and social care pathways for people with chronic disease. MS PDTAs were developed to achieve this goal through clarifying the diagnostic, therapeutic and care pathways in each region's unique health and social care context. PDTAs can therefore enable inter-regional monitoring, evaluation and quality improvement, and are key methods to reduce regional inequalities in care. However, not all regions have MS PDTAs, so guidelines are being discussed to encourage completion of PDTAs in the remaining regions and encourage alignment between the different PDTAs. This could occur through national evaluation and the establishment of an Italian MS observatory.



Case study 2

Standardising care and services for people with MS^{4 16 18 34}

Regional disparities mean that services and quality of care in different clinics can be variable. MS centres are formally incorporated in their respective hospitals and form part of a broader network committed to ensuring all people with MS receive appropriate and consistent care. The network encourages communication and high-quality care within and across regions, and over time it aims to overcome the disparities that exist in the surrounding health systems. PDTAs recognise the network model as important to providing consistent and equitable care. In the future, national recognition of the network will further improve coordination and planning.

Case study 3

Improving disability assessment in MS^{4 16 44}

Disability assessments are necessary for someone to receive practical or financial support from the government. However, such assessments often do not consider the 'invisible' symptoms of MS. To tackle this issue, AISM worked with Istituto Nazionale della Previdenza Sociale (INPS) and neurology associations to develop guidelines for the assessment of disability in people with MS. The guidelines provide assessment committees with the necessary information to fairly and consistently assess disability in a person with MS. First developed in 2012 and updated in 2018, they have been distributed by the INPS to all assessment committees and have been incorporated in five regional PDTAs. The guidelines seem to have had a positive impact as the AISM helpline has noted fewer people with MS believed that their disability has been unfairly assessed.



APPENDIX: ABOUT MS

MS is a complex and progressive disease of the central nervous system, where the immune system destroys brain, optic nerve and spinal cord tissue.¹⁻³ As a result, people with MS develop irreversible motor-disability and cognitive impairment over time.^{1 20 45} MS affects almost every aspect of day-to-day life,^{46 47} and its personal and economic impacts grow significantly as the condition progresses and disability worsens.^{3 48 49}

There are four main types of MS:

- **Clinically isolated syndrome (CIS)** is the first clinical presentation of inflammation or lesions.⁵⁰ However, many people with CIS will not go on to develop MS.⁵¹ If CIS becomes clinically active and fulfils the current diagnostic criteria, it can be reclassified as relapsing and remitting MS.⁵⁰
- **Relapsing and remitting MS (RRMS)** is characterised by intermittent ‘relapses’ (sudden onset of MS symptoms and disability), followed by remission periods where symptoms abate.^{52 53} Approximately 85–90% of people with MS have RRMS at diagnosis.^{2 52}
- **Secondary progressive MS (SPMS)** is characterised by progressive accumulation of disability after an initial relapsing course. There are no clear criteria to mark the transition between RRMS and SPMS, and often SPMS is only diagnosed retrospectively.⁵⁰
- **Primary progressive MS (PPMS)** is where disability accumulates without relapses from the outset.⁵⁰

MS can be a challenging condition to manage, due to its unpredictability and people’s changing healthcare needs.⁵⁴ Management strategies aim to reduce disease activity and development of disability but must be tailored to each person. They typically fall into three categories:

- DMTs
- Symptomatic therapies and rehabilitation
- Lifestyle interventions.



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