# The prevalence and direct costs of multiple sclerosis therapy in Poland from 2008 to 2016

# Chorobowość i koszty bezpośrednie terapii stwardnienia rozsianego w Polsce w latach 2008–2016

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Słowa kluczowe: stwardnienie rozsiane, epidemiologia, chorobowość, różnice regionalne.

# Abstract

Aim of the research: Analysis of prevalence of multiple sclerosis (MS) and direct healthcare costs of patients with MS in Poland between 2008 and 2016.

**Material and methods:** Retrospective analysis of data on healthcare services related to the treatment of patients with MS covered by National Health Fund (NHF) in 2008-2016. The Number of patients with MS, utilization of resources, and direct medical cost were analyzed for each year in 9-year time horizon. Costs were calculated from public payer perspective and reported in EuroPPP (adjusted for purchasing power parity).

**Results:** According to data from the NHF, the prevalence of MS in Poland was 103,06 and 113,06 per 100,000 population in 2008 and 2016, respectively. The annual growth rate of spending's on MS (+14%) was higher than the growth rate of patients (+1.3%). In the years 2008-2016, the average expenditure per patient increased from 2,800 to 6,900 EuroPPP. The largest group of patients was treated the out-patient setting (36% specialized, 29.3% primary care); however, 84% of funds were spent on hospital care. The main drivers for hospital costs were therapeutic/drug programs, which increased from 59 million in 2008 to 233 million EuroPPP in 2016. Currently, 25% of the MS population has access to publicly funded drug programs.

**Conclusions:** The situation of patients with MS in Poland is systematically improving. Over the past 9 years, both the public payer's expenditure on treatment of MS patients and the number of patients participating in drug programs funded by NHF have tripled.

# Streszczenie

**Cel pracy:** Ocena częstości występowania stwardnienia rozsianego (SM) oraz bezpośrednich kosztów leczenia pacjentów z SM w Polsce w latach 2008–2016.

**Materiał i metody:** Analiza retrospektywna danych dotyczących świadczeń opieki zdrowotnej związanych z leczeniem pacjentów z SM, finansowanych przez Narodowy Fundusz Zdrowia (NFZ) w latach 2008–2016. Dynamika liczby pacjen-

tów z SM, kosztów bezpośrednich udzielonych świadczeń oraz wykorzystania środków została przedstawiona w okresie dziewięcioletnim, przy czym dane uzyskano dla każdego roku z osobna. Podane koszty poniesione zostały przez płatnika publicznego (NFZ) i przeliczone według parytetu siły nabywczej euro (EuroPPP).

**Wyniki:** Według danych NFZ częstość występowania SM w Polsce wyniosła 103,06 i 113,06 na 100 000 mieszkańców kolejno w roku 2008 i 2016. Roczna stopa wzrostu wydatków na SM (+14%) była wyższa niż tempo wzrostu liczby pacjentów (+1,3%). W latach 2008–2016 średnie wydatki w przeliczeniu na pacjenta wzrosły z 2800 do 6900 EuroPPP. Największa grupa pacjentów była leczona w systemie ambulatoryjnym (36% – ambulatoryjna opieka specjalistyczna, 29,3% – podstawowa opieka zdrowotna), jednak 84% środków finansowych zostało przeznaczonych na opiekę szpitalną. Największą część kosztów szpitalnych stanowiły programy lekowe, których finansowanie wzrosło z 59 milionów EuroPPP w 2008 r. do 233 milionów EuroPPP w 2016 r. Szacunkowo 25% pacjentów z SM w Polsce ma dostęp do programów lekowych finansowanych ze środków publicznych.

**Wnioski:** Sytuacja pacjentów z SM w Polsce ulega systematycznej poprawie. W ciągu ostatnich 9 lat zarówno wysokość wydatków ponoszonych przez NFZ na leczenie pacjentów z SM, jak i liczba pacjentów uczestniczących w programach lekowych finansowanych ze środków publicznych uległy potrojeniu.

# Introduction

Multiple sclerosis (MS) is a chronic and highly disabling disease with heavy economic and social burdens [1–5]. A systematic review of the literature indicated that the mean utility scores varied between 0.80-0.92, 0.49-0.71, 0.39-0.54, and -0.19-0.1, for patients with Expanded Disability Status Scale (EDSS) scores of 0-1, 3, 6, and 8, respectively [6]. A negative value of health utility indicates that some patients with the highest disability defined their health state as worse than death. Treatments that delay disability progression can make positive impact on patients' quality of life.

In the recent years, significant progress has been made in Poland in the treatment of patients with MS. In 2011, the interferon therapy fully reimbursed by National Health Fund (NHF) as a drug program was extended from three to five years and in 2014, the duration of treatment was dependent on the clinical status of patients. In 2013, a drug program was introduced that allowed the use of a second-line disease-modifying drugs. Now in Poland, the following medications for moderately and highly active form of SM are reimbursed: interferon  $\beta$ -1, interferon  $\beta$ -2, peginterferon  $\beta$ -1a, glatiramer, teriflunomide, fingolimod, dimethyl fumarate, natalizumab, and alemtuzumab.

To assess the state of health care and actual needs in the area of MS treatment in Poland, accurate and up-todate estimates of the number of people affected by MS as well as the analysis of the organization and costs of each element of MS health care are required. Due to the lack of a nationwide registry of patients with MS, reliable data on MS epidemiology and costs can be obtained from the NHF database, which collects information on the health care services in conjunction with the patient's ID and the code identifying the reason for intervention. The aim of our study was to analyze MS morbidity as well as components of a comprehensive treatment plan for MS patients in the years 2008–2016, based on information on the utilization of health care services reported to the public payer.

# Material and methods

All types of healthcare services covered by public payer (NHF) in Poland in years 2009-2016 were retrospectively analyzed. From information reported to the NHF through the xml announcement [7] after performing medical procedures, only data linked to patients with MS (ICD-10: G35) were extracted. Based on the number of unique patient ID's (PESEL) diagnosed with SM (ICD10: G35), the annual and nine-year morbidity was estimated. We calculated the percentage proportion of patients "consuming" different categories of services (e.g. hospitalization, specialized care, primary care, rehabilitation, emergency, long-term care, psychiatric care, nursing care, transport) during the 9-year period. Direct costs were calculated from the public payer perspective and reported in EuroPPP (adjusted for purchasing power parity, Table 1), which

Indicator	Purchasing power parities for GDP							
Time	2009	2010	2011	2012	2013	2014	2015	2016
Unit	National currency per US dollar							
Country								
Poland (PLN)	1,87	1,8	1,8	1,8	1,76	1,76	1,76	1,75
Euro area (18 countries EU)	0,794	0,791	0,78	0,774	0,755	0,75	0,75	0,748

Table 1. PLN values converted to EuroPPP

Execution year	Number of patients with MS	The public payer expenditures on MS
2008	39,303	108,546,614
2009	42,676	153,106,618
2010	42,942	162,653,049
2011	43,699	166,893,488
2012	43,855	185,281,074
2013	43,876	202,939,676
2014	43,878	238,675,076
2015	43,685	275,914,351
2016	43,459	299,936,963
45 000	]	350 000

**Table 2.** Number of patients with multiple sclerosis (MS) and public payer expenditure on MS treatment in Poland from 2008 to 2016

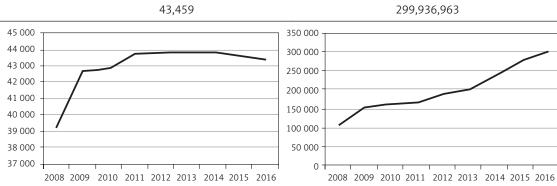
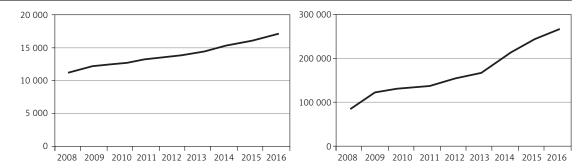


Table 3. Number of hospitalized multiple sclerosis (MS) patients and cost of MS hospitalizations in Poland from 2008 to 2016

Year	Number of hospitalized MS patients	The public payer expenditures on hospitalization of MS patients
2008	11,183	87,375,624
2009	12,194	122,321,492
2010	12,752	132,247,389
2011	13,154	138,154,016
2012	13,517	153,968,388
2013	14,429	170,539,505
2014	15,232	206,228,171
2015	16,137	241,705,978
2016	17,051	265,327,760



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Year	Number of patients	The value of settled billing units
2008	2,837	59,048,760
2009	3,592	86,810,319
2010	4,157	96,220,577
2011	4,608	104,998,277
2012	5,574	120,096,318
2013	6,801	138,619,323
2014	8,034	173,789,360
2015	9,319	209,124,312
2016	10,717	233,478,078
	12 000	350 000
	10 000	300 000
	8 000	250 000
	6 000	200 000
		150 000
	4 000	100 000
	2 000	50 000
	0	0

**Table 4.** Number of patients covered by multiple sclerosis (MS) drug programs and NHF expenditure for MS therapeutic programs in Poland in the years 2008–2016 as a part of drug programs

enabled omitting the values of inflation and exchange rate variations in the analysis. Mean cost per patient resulted from the total cost divided by the number of patients. Annual growth rates of the number of patients and costs were calculated. The results were presented in absolute numbers, frequency (in %) and graphically. The Pearson's correlation was used to test the association between the number of patients treated and costs. All calculations were performed using SAS EG 7.1 and MS Office 2016 software.

#### Results

The number of patients with MS in years 2008–2016 is presented in Table 2. During the analyzed period, there was 10.6% increase in the number of MS patients, and the dynamic of growth (year/year) was around +1.3%. In 2009, after complementary registration, the number of patients stabilized at 43.5 thousand with SD  $\pm$  3.4% in the period 2010–2016. The prevalence calculated based on the NHF data was 103,06 and 113,06 per 100,000 population in 2008 and 2016, respectively.

The public payer's spending on the treatment of MS during the 9-year period amounted to 1,794 million EuroPPP. The expenditures have steadily grown annually by an average of 14% (Table 2). The average spending per patient increased from 2,762 EuroPPP in 2008 to 6,902 EuroPPP in 2016 (+149.9%). The Pearson's correlation of 0.63 showed that strong positive correlation exists between the number of patients and the amounts spent on treatment of MS.

Figure 1 shows the percentage proportion of patients "consuming" each specific category of services during the 9-year period. The largest group of patients was treated in the out-patient setting: specialized (36%), primary care (29.3%), and 18.4% of patients were hospitalized.

In terms of costs, the main item was hospitalization (84.2% of costs), followed by rehabilitation (6.8% of costs), and nursing care (5.5% of costs). For specialized ambulatory care, the NHF spent only 2.3% of total MS budget (Figure 2).

Between 2008 and 2016, the number of hospitalized patients increases by 52.5% (by 5.4% annually), from 11,183 to 17,051, while NHF spending for hospitalizations has risen by 203.7% (by 15.5% annually), from 87,375,624 EuroPPP to 265,327,760 EuroPPP (Table 3). The mean yearly cost of in-patient care per patient was in 2016 two times higher than in 2008: 15,561 EuroPPP vs. 7,813 EuroPPP, and mean annual growth rate was 9.3%.

A separate path within in-patient care are therapeutic programs covered by the public payer.

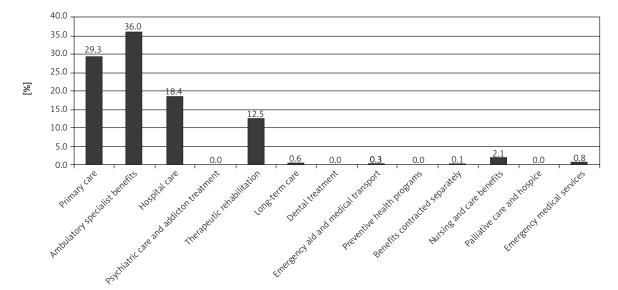


Figure 1. The percentage proportion of patients consuming specific category of health care services in the period 2008–2016

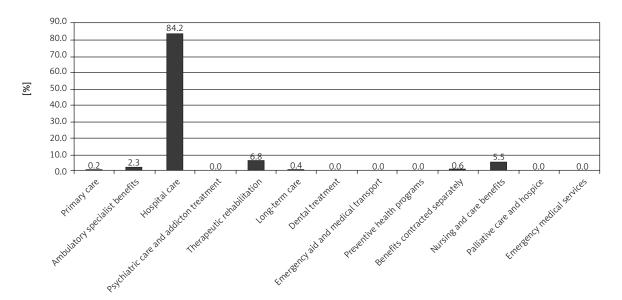


Figure 2. The percentage proportion of multiple sclerosis costs by different categories of services in the period 2008–2016

The number of patients who benefit from these therapies have steadily grown from under 3,000 (25.4% of hospitalized patients) in 2008 to over 10,000 (63% of hospitalized patients) in 2016 (Table 4). Utilization of disease modifying therapies was the main driver of costs reaching 80–90% of total NHF expenditure for hospitalizations associated with MS. For the implementation of MS drug programs throughout the analyzed period, NHF spent in total 1,222 mln EuroPPP, which constitutes 68% of the total budget on MS. Both the number of patients treated and the spending on therapeutic/drug programs indicate positive periodic dynamic rate (+277.8% and +295.4%, respectively) and an average annual rate (+18.2% and +19.3%, respectively) and are strongly positively correlated (Pearson's correlation coefficient = 0.99547). The mean cost per patient remained at similar level: 20,814 in 2008 and 21,786 in 2016.

# Discussion

Our study revealed that over the past 9 years, public payer's annual expenditures on the treatment of MS patients were continuously rising. The average spending per patient increased by 150%, from 2,762 EuroPPP in 2008 to 6,902 EuroPPP in 2016. Although the largest group of patients was treated in out-patient settings (36% specialized, 29.3% primary care), 84% of funds was allocated to the in-patient care. Such a breakdown of expenses is because the drug programs are funded through hospital procedures. Therapeutic/drug programs were the main drivers for both the total MS expenditures and hospital cost, accounting for 68% and 80–90%, respectively. Although according to the data published by the European MS Platform [8], the percentage of Polish MS patients who receive the disease modifying therapy still belongs within the lowest in Europe, the situation of Polish MS patients is steadily improving. Currently, 25% of the MS population has access to publicly funded drug programs, three times more than 9 years back.

Expenditures on the rehabilitation treatment were relatively low (6.8% of total spending) and a low percentage of people received such benefits (12.5%). This is probably due to the lack of reliable evidence on the effectiveness of rehabilitation treatments for MS [9, 10], although many clinicians and patients consider that the comprehensive individualized rehabilitation improves patients' quality of life [11].

The strength of our study is that it is based on the data from the entire Polish population and includes a long, 9-year time horizon. Unfortunately, the scope of data collected routinely by the public payer was limited and did not allow to conduct a distinction between types of MS as well as individual stages of disease progression. Like other administrative database-based studies, it does not contain information about patients' clinical state, making it impossible to directly assess the impact of the use of various therapies on health outcomes. Since the analyzed data only relate to the public payer's spending, our study does not include out-of-pocket costs (expenses that aren't reimbursed by insurance) and indirect costs. Despite these limitations, the results of our research provide useful information on the number of patients with MS and the organization of their treatment in Poland, and may also serve as a basis for planning further actions to improve the care of patients with MS.

## **Conflict of interest**

The authors declare no conflict of interest.

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