# The Rising Cost of Specialty Drugs Drove Spending Increases for People with Multiple Sclerosis

How does the cost of prescription drugs affect the cost of care for individuals who rely on them? HCCl investigated how the cost of prescription drugs affects the total cost of care for people with multiple sclerosis (MS). MS is a central nervous system disease <u>estimated</u> to affect over 400,000 people in the U.S., costing an estimated \$10 billion in health care spending each year. The <u>rising prices</u> of specialty drugs used to treat MS, called disease modifying therapies (DMTs), garnered <u>media attention</u>. The U.S. House of Representatives began <u>investigating DMT</u> prices. The role prescription drugs play in affecting the cost of care for people with diseases like MS will become more important as policy makers consider <u>relaxing consumer protections</u> created by the Affordable Care Act.

**What We Did.** HCCI analyzed claims for people diagnosed with MS from 2009 to 2015. We limited our sample to individuals flagged with an MS diagnosis with 12 months of continuous insurance enrollment and prescription drug coverage. Our sample comprises individuals from the individual, employer sponsored health insurance, and Medicare Advantage markets. We aggregated total health care spending – the sum of negotiated payer spending and individuals' out-of-pocket spending – and utilization for individuals within each year.

### **Questions We Asked.**

- 1. How did health care spending for people diagnosed with MS change from 2009 to 2015?
- 2. Which drugs drove changes in spending on Disease Modifying Therapies (DMTs)?
- 3. How did the use of DMTs change for people with MS?
- 4. Was increased spending on oral DMTs driven by changes in use or cost?
- 5. How did the cost of DMTs change from 2009 to 2015?

**What We Found.** For people with MS, total health care spending per person nearly doubled from 2009 to 2015. Disease modifying therapies (DMTs) accounted for 82% of the increase in total spending. Overall DMT spending more than doubled from 2009 to 2015, primarily due to a rise in spending on newly introduced oral DMTs. Overall DMT use was slightly lower in 2015 than in 2009. Further, the average cost for each DMT studied rose by an average of between 9% and 23% per year from 2009 to 2015. While we do not provide causal evidence, our results suggest that the rising cost of DMTs were the primary driver of increased prescription drug spending - and total health care spending - for people with MS.

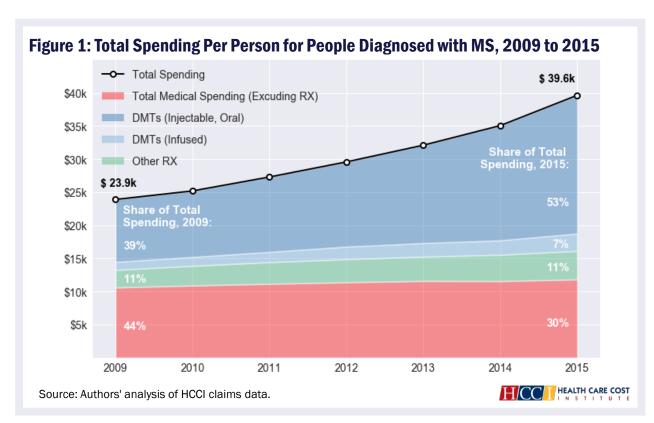
On the other hand, overall DMT use did increase from 2012 to 2015 as the use of oral DMTs increased following their introduction. This increase in DMT use represents a potentially positive development to weigh against increased DMT spending from 2012 to 2015.



### How did health care spending for people diagnosed with multiple sclerosis (MS) change from 2009 to 2015?

### Health care spending per person nearly doubled from 2009 to 2015, driven by increased spending on disease modifying therapies (DMTs)

We decomposed total health care spending – the sum of payer spending and individuals' out-of-pocket spending – for people diagnosed with MS into spending on one of the following: medical services (inpatient, outpatient, professional services), DMTs (a specific class of specialty drugs used to treat MS), or all other prescription drugs (Figure 1, <u>Table 1</u>).



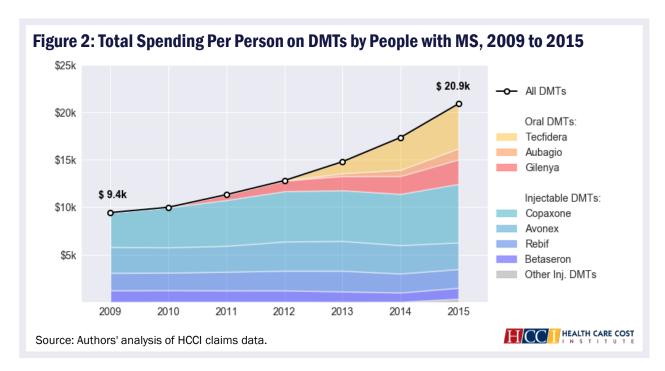
- By 2015, total spending per person for people with MS was \$39,628:
  - \$11,820 in medical spending (excluding all prescription drugs)
  - \$20,882 in spending on injectable, oral DMTs
  - \$2,613 in spending on infused DMTs
  - \$4,312 in spending on all other prescription drugs

- DMTs accounted for 82% of the increase in total spending for people with MS from 2009 to 2015.
- By 2015, more than half (53%) of all health care spending for people with MS went towards injectable and oral DMTs.
- The share of spending on all medical services (besides prescription drugs) dropped from 44% to 30% despite increased medical spending from 2009 to 2015.



## Spending on DMTs more than doubled from 2009 to 2015, primarily due to a rise in spending on newly introduced oral DMTs

To better understand how spending on DMTs changed from 2009 to 2015, we decomposed total spending per person on DMTs by each specific DMT (Figure 2, Table 2).



- Spending on Copaxone the DMT with the highest spending per person – increased from \$3,634 per person in 2009 to \$6,163 in 2015.
- Other injectable DMTs of note either saw minimal increases in spending per person (Avonex, Rebif) or slight declines (Betaseron) from 2009 to 2015.
- From 2009 to 2015, three oral DMTs were introduced: Gilenya (2010), Aubagio (2012), and Tecfidera (2013).
- By 2015, Tecfidera had the second highest per person spending of any DMT, \$4,706.
- From their introduction to 2015, oral DMTs accounted for:
  74% of the increase in DMT spending: Tecfidera (41%), Gilenya (23%), Aubagio (10)
  54% of the increase in overall spending: Tecfidera (30%), Gilenya (16%), Aubagio (7%)

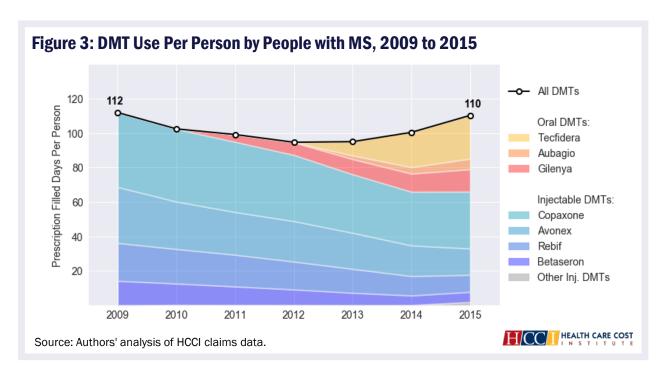
<u>Methods note:</u> In Figures 2 and 3, "All DMTs" refers to total per person spending on and use of injectable and oral DMTs. In particular, these figures omit spending on and use of infused DMTs. For further explanation, see the <u>Methods</u> section.



### How did the use of Disease Modifying Therapies (DMTs) change for people with MS?

## While overall DMT use was slightly lower in 2015 than in 2009, individuals shifted to using new oral DMTs

To understand how DMT use changed from 2009 to 2015, we plotted the number of prescription filled days per person with MS for each DMT (Figure 3, Table 3).



While which DMTs people used changed, overall DMT use experienced a slight decline from 2009 to 2015. This suggests that the average cost of DMTs increased from 2009 to 2015.

- By 2015, Tecfidera was the second most used DMT in our sample – 25 filled days per person – despite its introduction in 2013.
- Due to increased use of oral DMTs, overall DMT use increased from 95 filled days per person in 2012 to 110 in 2015 (17%).
- The overall increase in DMT use from 2012 to 2015 represents a potential benefit to weigh against the overall increase in spending on DMTs over this time frame.

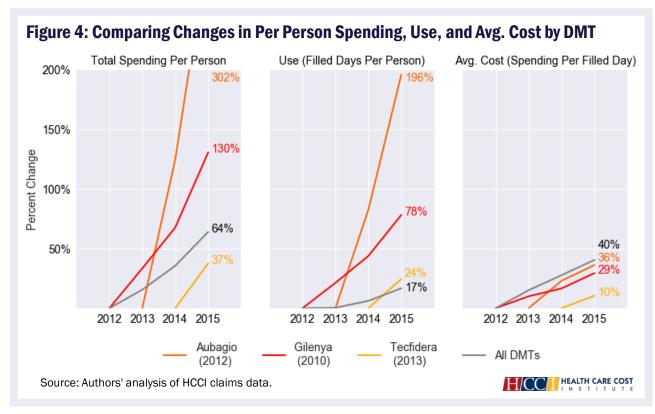
- Overall, use of injectable DMTs declined from 2009 to 2015:
  - Avonex, 53% decrease
  - Copaxone, 24% decrease
  - Betaseron, 58% decrease
  - Rebif, 55% decrease
- Decreased use of injectable DMTs coincided with either increases or marginal decreases in spending. For a further discussion, see the Appendix.



### Was increased spending on oral Disease Modifying Therapies (DMTs) driven by changes in use or cost?

## Increased spending on newer, oral DMTs was primarily driven by increased use despite increases in their cost

Both spending on and use of oral DMTs (Aubagio, Gilenya, and Tecfidera) increased since their introduction to 2015. To understand changes in spending on each newly introduced oral DMT, we decomposed total spending per person into use (filled days per person) and average cost (total spending per filled day) (Figure 4).



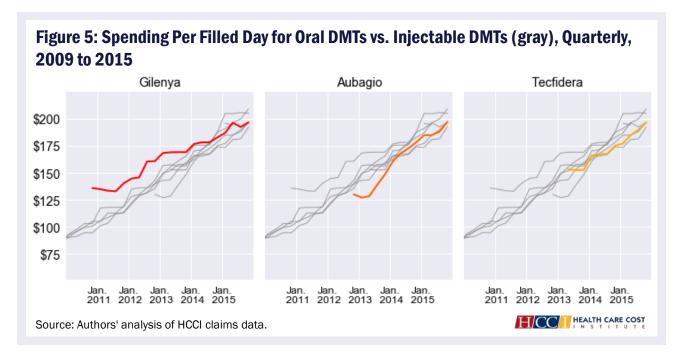
From the respective introductions of Aubagio, Gilenya and Tecfidera to 2015:

- By 2015, oral DMTs accounted for 40% of all DMT filled days (Figure 3).
- Each experienced larger changes in use than changes in the average cost, implying that increases in spending were primarily due to increased use.
- Still, the average cost of each DMT increased by an average of almost 10% per year.
- Changes in use for each DMT were primarily due to changes in the number of people using each DMT, rather than the amount of each DMT people were using.
- Similar plots for older, injectable DMTs can be found in the <u>Appendix</u>.



# The average cost of DMTs more than doubled from 2009 to 2015, rising similarly for each DMT

From 2009 to 2015, spending on DMTs increased (<u>Figure 2</u>) and overall use remained similar (<u>Figure 3</u>), implying that the average cost of DMTs increased. However, there was also a shift towards using to newly introduced oral DMTs. To explore whether the average cost of DMTs rose due to a change in which DMTs people were taking, we compared the total spending per filled day for each DMT, highlighting oral DMTs (Figure 5, <u>Table 4</u>). Here, total spending refers to the sum of negotiated payer spending plus individuals' out-of-pocket spending.



- Spending per filled day for the average DMT more than doubled from 2009 to 2015. The cost of each DMT followed similar increases, averaging between 9% and 23% per year.
- By 2015, a filled day of Gilenya cost \$197. This translates to \$5,503 for a month's supply. Table 5 reports the cost of a month's supply for each DMT.
- The similar increases in the cost of each DMT suggest that the average cost of DMTs increased primarily because each DMT became more expensive from 2009 to 2015, rather than changes in which DMTs people with MS used.

<u>Methods Note:</u> The cost per filled day data reported above are quarterly averages of total spending per day on the most common NDC code for each DMT. For this reason, the average cost per filled day plotted in Figure 5 are slightly different than Figure 4. For more information, see the <u>Methods</u> section. For similar plots for the older, injectable DMTs, see the <u>Appendix</u>.



#### **Data and methods**

#### Sample Construction:

Using HCCI claims data from 2009 to 2015, we flagged individuals as diagnosed with multiple sclerosis (MS) if they had a claim with either an ICD-9 diagnosis code for MS (340) or a MS-DRG code (058, 059, 060). Once flagged, individuals remained flagged for the duration of our sample. We omitted claims prior to the initial diagnosis. We limited our sample to person, year observations of individuals flagged with an MS diagnosis with 12 months of continuous insurance enrollment and prescription drug coverage. Our sample is best thought of as a repeated cross section ranging from 42,279 people in 2009 to 58,608 in 2015. Our sample comprises individuals from the individual, employer-sponsored health insurance, and Medicare Advantage markets. Around 75% of the sample are female. In our sample, 10% of person, year observations are under the age of 35, 73% of people are between the ages of 35-64, and 17% are over the age of 65.

We aggregate total spending – the sum of payer spending and individuals' out-of-pocket spending within each year. We decompose total spending into spending on all medical services (inpatient admissions, outpatient services, and professional services), and prescription drug spending. We further decompose prescription drug spending into spending on disease modifying therapies (DMTs) and all other prescription drugs. To calculate spending on infused DMTs, we aggregate all medical spending on days on which an individual receives an infusion as spending on infused DMTs. We further reclassify them as spending on disease modifying therapies. We decomposed spending on DMTs by the type of each DMT. Throughout the brief we report per person numbers which are the sum of total spending on or use of each DMT divided by the number of individuals in the sample in each year. Importantly, this measure is distinct from spending per person taking each drug. All dollars values reported are nominal.

#### **DMT Classification:**

We categorized drugs as DMTs in accordance with <u>Hartung et al. (2015)</u>, and following publications from the <u>National Multiple Sclerosis Society</u>. Throughout the brief we report spending and use per person for the most common DMTs over the duration of our sample. We group all remaining injectable DMTs taken by people in our sample as "other injectable DMTs" (Extavia, Glatopa, and Plegridy). We categorize infused DMTs (Tysabri, Lemtrada, and Novantrone) separately from oral and injectable DMTs because they are administered differently than prescription drugs; their use is measured in the number of days with an administered infusion rather than prescription filled days. To facilitate the comparison of spending and use per person we omit spending and use of infused DMTs from our analysis on pages 2 and 3. As seen in Figure 1, though, infused DMTs are not a leading driver of increased health care costs for people with MS in our sample from 2009 to 2015.



### **Data and methods (continued)**

#### Calculating Average Cost for Each DMT:

To measure average cost of each DMT, we computed total spending per filled day. Total spending refers to the sum of negotiated payer spending plus individuals' out-of-pocket spending per filled day. To calculate the spending per filled day reported in Figure 5, we used subset of prescription drug claims by people with MS in our sample. To address potential outliers, we limited the subset of our sample to claims for the most common amount of filled days for each NDC code for each DMT. To account for the possibility that drugs change formulations over time, we used the most frequently used NDC code in our sample for each DMT. For each claim we divided total spending by the number of prescription filled days. We subsequently took the quarterly average for each DMT to compute the average cost per filled day for each DMT used in Figure 5, Table 4. The average cost per month's supply in Table 5 is computed as the product of the average cost per filled day by the most common amount of filled days for each NDC code for each DMT.

Due to this procedure, the spending per filled day plotted in Figure 5 and reported in Table 4 are slightly different than the yearly average spending per filled day used to compute percent changes from 2012 to 2015 in Figure 4. In Figure 4, average cost was computed as total spending by people with MS on each DMT divided by the total number of filled days used by people with MS on each DMT in each year; this included data from all NDC codes and for all prescriptions filled for each DMT.



#### **Limitations**

This study has several limitations that affect the interpretation of the findings presented. This brief presents per person spending and use trends for adults flagged as diagnosed with multiple sclerosis (MS) and those not flagged as being diagnosed with MS. Because this study was based on claims data, HCCl could not identify individuals with MS who did not file medical claims with their health insurer or had undiagnosed MS. Therefore, individuals identified in this dataset as having MS are by construction more likely to have any health care spending than the average adult with MS.

It is important to note that over 60% of people in our sample appear in multiple years. Consequently, it is possible that the trends reported in this issue brief may reflect increases in the cost of care as individuals' course of MS progresses as well as changes in the cost of care for all individuals with MS. While we see evidence that changes in health care spending in our sample were not driven by changes in the demographic make up of our sample, we do not test for this possibility directly.

The findings in this study are descriptive and not causal. In particular, we did not account for the direction of the relationship between a MS diagnosis and spending. Further, while our results provide evidence, for example, that the cost of disease modifying therapies rose over our sample time period, we do not assign causality to changes in the cost of such drugs and changes in spending on them or their use. HCCI considers its work a starting point for analysis and research on health care spending for people diagnosed with MS.

Throughout the issue brief, we focus on total health care spending – the sum of payer spending and individuals' out-of-pocket spending. Total health care spending on prescription drugs cannot account for any rebates received by payers for prescription drugs. We also cannot account for any out-of-pocket assistance received by patients which may affect their true out-of-pocket burden. Consequently, the changes in total spending we report here may overstate the true changes in the cost of care payers face in covering individuals with MS, and individuals may face to cover the cost of their own care.

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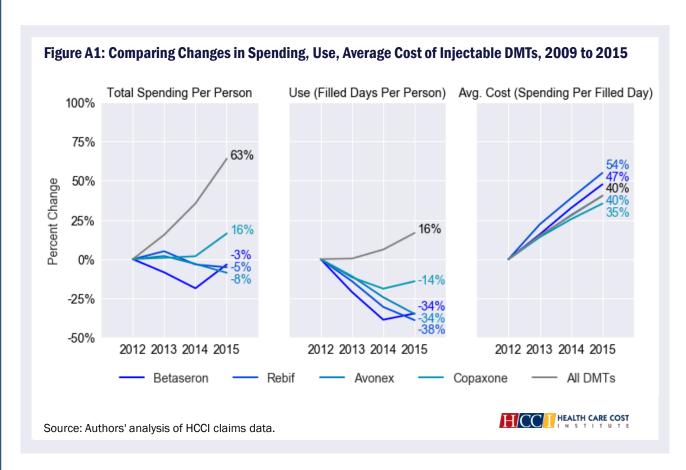
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# Changes in spending on older, injectable DMTs was primarily due to changes in their cost

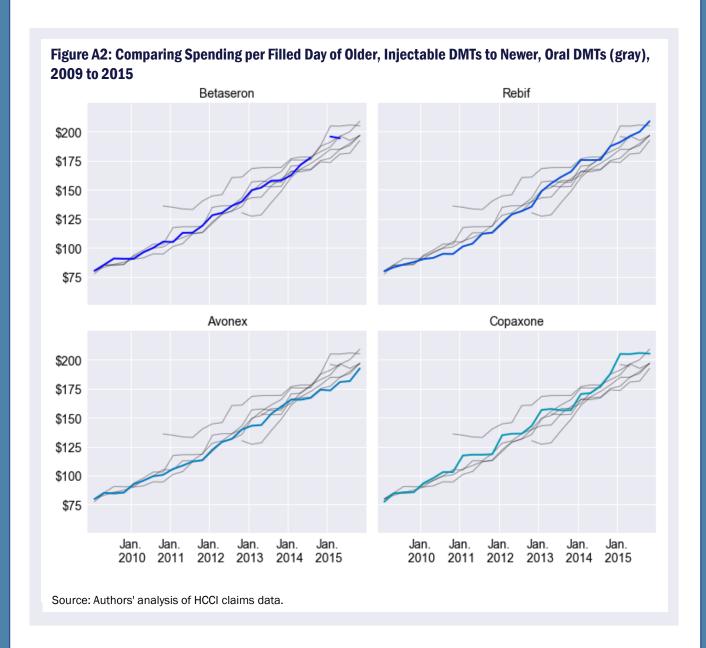
To understand changes in spending on each DMT we decomposed total spending per person into use (filled days per person) and average cost (total spending per filled day).



- Use of Avonex, Betaseron, Copaxone, and Rebif declined from 2012 to 2015 (Figure A1, <u>Table 3</u>).
- Despite the decline in their use, injectable DMTs still accounted for 60% of all DMT filled days in 2015 (<u>Figure 3</u>).
- The average cost of each injectable DMT increased from 2012 to 2015. Spending per filled day increased an average of around 10% per year for each injectable DMT.
- Due to the increase in their average cost, changes in spending on each older, injectable
  DMT did not match their decreased use from 2012 to 2015.



### The average cost of injectable DMT rose similarly from 2009 to 2015



<u>Methods Note:</u> Spending per filled day reported above are quarterly averages of total spending per filled day on the most common NDC code for each DMT. Values that aggregate fewer than 10 observations are censored. For more information, see the <u>Methods</u> section.





Table 1: Total Spending Per Person Diagnosed with MS by High Level Service Category, 2009 to 2015

Service Category	2009	2010	2011	2012	2013	2014	2015
Total	\$23,890	\$25,184	\$27,286	\$29,564	\$32,087	\$35,050	\$39,628
Medical Total	\$10,601	\$10,907	\$11,153	\$11,391	\$11,590	\$11,562	\$11,820
Inpatient	\$2,821	\$3,149	\$3,208	\$3,325	\$3,352	\$3,421	\$3,202
Outpatient	\$3,059	\$3,209	\$3,368	\$3,506	\$3,599	\$3,694	\$3,934
Professional Services	\$4,721	\$4,550	\$4,577	\$4,560	\$4,638	\$4,448	\$4,684
DMT Total	\$10,638	\$11,309	\$12,862	\$14,685	\$16,823	\$19,507	\$23,496
Injectable	\$9,420	\$9,963	\$10,731	\$11,664	\$11,766	\$11,380	\$12,432
Oral	\$0	\$15	\$583	\$1,133	\$3,014	\$5,949	\$8,450
Infused	\$1,219	\$1,331	\$1,548	\$1,888	\$2,043	\$2,178	\$2,613
All Other RX	\$2,651	\$2,968	\$3,270	\$3,488	\$3,675	\$3,980	\$4,312



Table 2: Total Spending Per Person Diagnosed with MS on Disease Modifying Therapies (DMTs), 2009 to 2015 (Excluding Infused DMTs)

DMT:	2009	2010	2011	2012	2013	2014	2015
DMT Total (Excluding Infused)	\$9,420	\$9,978	\$11,314	\$12,797	\$14,780	\$17,330	\$20,882
DMT Injectable	\$9,420	\$9,963	\$10,731	\$11,664	\$11,766	\$11,380	\$12,432
Avonex	\$2,719	\$2,671	\$2,726	\$3,077	\$3,138	\$2,984	\$2,811
Betaseron	\$1,221	\$1,213	\$1,200	\$1,194	\$1,094	\$973	\$1,154
Copaxone	\$3,634	\$4,207	\$4,824	\$5,299	\$5,342	\$5,399	\$6,163
Rebif	\$1,845	\$1,855	\$1,963	\$2,076	\$2,181	\$2,006	\$1,968
Other DMT	\$1	\$19	\$18	\$18	\$11	\$19	\$336
DMT Oral		\$15	\$583	\$1,133	\$3,014	\$5,949	\$8,450
Aubagio				\$10	\$288	\$646	\$1,159
Gilenya		\$15	\$583	\$1,122	\$1,496	\$1,880	\$2,585
Tecfidera					\$1,229	\$3,424	\$4,707



Table 3: Prescription Filled Days Per Person Diagnosed with MS of Disease Modifying Therapies (DMTs), 2009 to 2015

DMT:	2009	2010	2011	2012	2013	2014	2015
DMT Total (Excluding Infused)	112	102	99	95	95	100	110
DMT Injectable	112	102	95	87	76	66	66
Avonex	33	28	25	24	21	18	15
Betaseron	14	12	11	9	7	6	6
Copaxone	43	42	41	38	34	31	33
Rebif	22	20	18	16	14	11	10
Other DMT	0	0	0	0	0	0	2
DMT Oral			4	7	19	35	44
Aubagio				0	2	4	6
Gilenya		0	4	7	9	10	13
Tecfidera					8	20	25



Table 4: Average Cost (Total Spending Per Filled Day) of the most common NDC code for each DMT by Quarter, 2009 to 2015

Year	Quarter	Aubagio	Avonex	Betaseron	Copaxone	Gilenya	Rebif	Tecfidera
2009	1		\$80	\$80	\$78		\$80	
2009	2		\$85	\$85	\$85		\$83	
2009	3		\$85	\$91	\$86		\$86	
2009	4		\$85	\$90	\$86		\$88	
2010	1		\$93	\$90	\$94		\$90	
2010	2		\$96	\$96	\$98		\$91	
2010	3		\$99	\$100	\$103		\$95	
2010	4		\$101	\$105	\$103	\$136	\$95	
2011	1		\$106	\$105	\$117	\$135	\$101	
2011	2		\$109	\$113	\$118	\$133	\$103	
2011	3		\$112	\$113	\$118	\$133	\$112	
2011	4		\$113	\$119	\$118	\$140	\$113	
2012	1		\$122	\$128	\$135	\$145	\$121	
2012	2		\$129	\$130	\$136	\$146	\$129	
2012	3		\$132	\$136	\$136	\$160	\$132	
2012	4	\$130	\$140	\$140	\$143	\$161	\$135	
2013	1	\$127	\$143	\$150	\$157	\$168	\$149	
2013	2	\$128	\$144	\$152	\$157	\$169	\$155	\$153
2013	3	\$139	\$153	\$158	\$156	\$169	\$161	\$152
2013	4	\$149	\$159	\$158	\$156	\$169	\$165	\$153
2014	1	\$161	\$165	\$162	\$170	\$177	\$175	\$166
2014	2	\$168	\$165	\$171	\$171	\$178	\$175	\$167
2014	3	\$172	\$167	\$177	\$177	\$178	\$176	\$168
2014	4	\$178	\$174		\$188	\$183	\$187	\$175
2015	1	\$185	\$173	\$196	\$205	\$187	\$191	\$177
2015	2	\$185	\$181	\$194	\$205	\$196	\$196	\$185
2015	3	\$188	\$181		\$206	\$192	\$200	\$190
2015	4	\$197	\$192		\$205	\$197	\$209	\$197



Table 5: Average Cost (Total Spending) Per Month's Supply of the most common NDC code for each DMT by Quarter, 2009 to 2015

Year	Quarter	Aubagio	Avonex	Betaseron	Copaxone	Gilenya	Rebif	Tecfidera
2009	1		\$2,233	\$2,243	\$2,326		\$2,233	
2009	2		\$2,384	\$2,385	\$2,540		\$2,327	
2009	3		\$2,369	\$2,539	\$2,570		\$2,394	
2009	4		\$2,390	\$2,532	\$2,572		\$2,451	
2010	1		\$2,594	\$2,534	\$2,805		\$2,526	
2010	2		\$2,678	\$2,690	\$2,935		\$2,553	
2010	3		\$2,786	\$2,797	\$3,092		\$2,652	
2010	4		\$2,820	\$2,944	\$3,091	\$3,804	\$2,648	
2011	1		\$2,961	\$2,937	\$3,520	\$3,775	\$2,829	
2011	2		\$3,041	\$3,158	\$3,541	\$3,735	\$2,897	
2011	3		\$3,140	\$3,161	\$3,541	\$3,720	\$3,136	
2011	4		\$3,174	\$3,330	\$3,553	\$3,926	\$3,162	
2012	1		\$3,426	\$3,583	\$4,045	\$4,049	\$3,385	
2012	2		\$3,614	\$3,640	\$4,082	\$4,080	\$3,603	
2012	3		\$3,688	\$3,810	\$4,084	\$4,491	\$3,682	
2012	4	\$3,642	\$3,913	\$3,913	\$4,285	\$4,501	\$3,790	
2013	1	\$3,557	\$4,003	\$4,188	\$4,699	\$4,710	\$4,163	
2013	2	\$3,594	\$4,020	\$4,249	\$4,723	\$4,731	\$4,350	\$4,595
2013	3	\$3,887	\$4,291	\$4,416	\$4,689	\$4,734	\$4,506	\$4,573
2013	4	\$4,160	\$4,464	\$4,422	\$4,692	\$4,734	\$4,634	\$4,583
2014	1	\$4,494	\$4,632	\$4,546	\$5,109	\$4,945	\$4,914	\$4,976
2014	2	\$4,698	\$4,631	\$4,802	\$5,131	\$4,986	\$4,913	\$5,016
2014	3	\$4,829	\$4,675	\$4,970	\$5,313	\$4,987	\$4,916	\$5,025
2014	4	\$4,987	\$4,872		\$5,629	\$5,114	\$5,246	\$5,249
2015	1	\$5,172	\$4,856	\$5,480	\$6,144	\$5,231	\$5,346	\$5,313
2015	2	\$5,173	\$5,058	\$5,440	\$6,140	\$5,496	\$5,487	\$5,540
2015	3	\$5,264	\$5,080		\$6,169	\$5,386	\$5,596	\$5,692
2015	4	\$5,515	\$5,386		\$6,151	\$5,503	\$5,851	\$5,898