Real–World Cost of Care, Treatment Completion and Site of Care Cost for Patients with Multiple Sclerosis Initiating Infused Disease–Modifying Therapies

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Background

- Expenditures for intravenous (IV) disease modifying therapies (DMTs) for multiple sclerosis (MS) include costs beyond wholesale acquisition price (WAC) such as costs for administration, monitoring, co–administered medications such as corticosteroids, clinician visits, and management of adverse events during infusion[1]. These costs may also vary depending on the infusion center setting (site of care).
- Cost of IV DMTs is usually calculated from WAC along with cost of administration and monitoring calculated via physician fee schedules may underestimate the actual amounts paid by US payers and consequently the budget impact of the DMTs.[1]
- Real–world cost of IV DMTs during the first year of treatment was estimated in a recently published study.[1] This study aims to comprehensively understand the real–world long–term (over 2 years) total cost of care (drug + infusion + other medical costs) for IV DMTs.

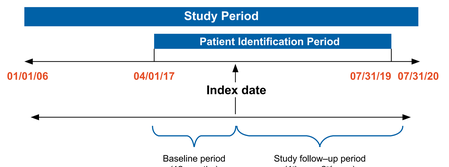
Objectives

- To evaluate the real–world total cost of care (direct pharmacy and medical costs) over 2 years, for MS patients who initiate ocrelizumab (OCR), natalizumab (NTZ), alemtuzumab (ATZ) (IV DMTs) in the United States of America (USA) and complete yearly dosing schedules according to FDA approved prescribing information.
- To assess real–world total cost of care for OCR, NTZ, and ATZ by site of administration (during follow–up) and cross–sectionally assess trend in site of care for OCR over time.
- To explore differences in total cost of care for before and after switching to OCR, NTZ and ATZ.

Methods

- This was a retrospective observational cohort study of MS patients initiating IV DMT's including OCR, NTZ, and ATZ. The study used data from the HealthCore Integrated Research Database (HIRD®). HIRD® is a broad and geographically diverse repository of longitudinal medical and pharmacy claims data from health plan members across the USA, representing over 50 million lives of commercially insured and Medicare advantage members.
- Study patients were identified based on the observed presence of any medical or pharmacy claim for an IV DMT between 4/1/2017 and 7/31/2019. Study outcome measures were collected for the study period between 1/1/2006 and 7/31/2020. The first observed use of DMT of interest was regarded as the index drug and that date was regarded as the index date. **Figure 1** summarises the study setting for identification of study population.

Figure 1. The study design scheme for identification of study population



- Patients aged ≥18 years with ≥1 medical claim for MS during baseline period, including index date, and ≥12 months of continuous medical and pharmacy enrolment preceding the index date (baseline period) and following the index date were included. Patients with any prior use of an index IV DMT, or claims for multiple DMTs on index date were excluded.
- Total costs of care (inclusive of medical costs and pharmacy cost) at baseline and during 1st and 2nd year follow–up period, detailed cost of care by site of care, trend for sites of infusions for OCR over time and cross–sectional snapshot every 6 months, pre-post OCR switch cost analysis, dosing schedule completion for first– and second year, and baseline demographic, clinical and treatment characteristics were assessed.
- Costs were adjusted to 2019 dollars.
- All study data were accessed using techniques compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and no identifiable or protected health information was extracted for the study.

Results

- Among 77,372,135 HIRD® data lives, 1,058 patients were identified in OCR cohort, 166 in NTZ cohort and 46 patients in the ATZ cohort. **Table 1** presents the details pertaining to patient selection during the patient identification period.

Table 1. Patient's selection as per the inclusion and exclusion criteria

	Criteria	Counts		
1	Total HIRD® data sample	77,372,135		
2	≥ 1 medical claim for MS at any time*	56,412		
3	**Cohort criteria**	**OCR**	**NTZ**	**ATZ**
3.1	≥ 1 DMT of interest between 04/01/2017 and 07/31/2019 (index date)	2,260	1,747	159
3.2	≥ 12 months of pre–index continuous medical and pharmacy enrollment (baseline period)	1,469	986	110
3.3	≥ 12 months of post–index continuous medical and pharmacy enrollment	1,060	672	76
3.4	≥ 1 medical claim with a diagnosis for MS on the index date or during baseline period	1,060	672	76
3.5	Age ≥ 18 years on index date	1,060	671	76
3.6	Excluded patients with multiple DMTs on index date	1,058	671	76
3.8	Excluded patients with any prior index DMT of interest use any time prior to the index date	**1,058**	**166**	**46**

ATZ: alemtuzumab; DMT: disease–modifying therapies; HIRD®: HealthCore Integrated Research Database; MS: multiple sclerosis; NTZ: natalizumab; OCR: ocrelizumab. *Only commercially insured patients were included.

- The majority of patients across the three–treatment cohorts were females (63%–74%) and aged between 35–54 years. The key demographic, clinical, and treatment characteristics of the patients are presented in **Table 2.**
- Nearly 50% of the patients in OCR and NTZ cohorts and around 60% of the patients in ATZ cohort had experienced at least one MS relapse at baseline.
- The use of DMTs at baseline was the highest among ATZ cohort (89.1%), while nearly 60% of the patients in OCR and NTZ cohort reported the use of DMTs at baseline.

Table 2. Patient demographics and baseline clinical and treatment characteristics

	OCR	NTZ	ATZ
Number of patients, n (%)	1,058	166	46
Age on index date (years), mean (SD)	46.3 (10.6)	42.9 (10.4)	43.3 (9.7)
Age categories, n (%)			
18–34	154 (14.6)	36 (21.7)	<10
35–44	303 (28.6)	52 (31.3)	19 (41.3)
45–54	344 (32.5)	56 (33.7)	13 (28.3)
55–64	231 (21.8)	20 (12)	<10
65+	26 (2.5)	<10.0	0 (0)
Gender, n (%)			
Female	710 (67.1)	123 (74.1)	29 (63.0)
Residence region, n (%)			
Midwest	284 (27.3)	45 (27.3)	13 (28.3)
Northeast	210 (20.2)	29 (17.6)	<10
South	267 (25.6)	48 (29.1)	26 (56.5)
West	280 (26.9)	43 (26.1)	<10
Other/unknown	17 (1.6)	<10	0 (0)
Plan type, n (%)			
Health maintenance organization	232 (21.9)	33 (19.9)	<10
Preferred provider organization	498 (47.1)	81 (48.8)	26 (56.5)
Consumer–driven health plans	181 (17.1)	26 (15.7)	<10
Others	147 (13.9)	26 (15.7)	<10
Year of index drug claim, n (%)			
2017	262 (24.8)	65 (39.2)	15 (32.6)
2018	565 (53.4)	72 (43.4)	22 (47.8)
2019	231 (21.8)	29 (17.5)	<10
Length of follow–up in months, mean (SD)	24 (7.1)	24 (7.8)	24 (7.6)
Proportion of patients with 2 years of follow–up, n (%)	526 (49.7)	77 (46.4)	22 (47.8)
Quan–Charlson Index comorbidity score, mean (SD)	0.56 (1.1)	0.42 (0.9)	0.39 (1.4)
MS relapse, n (%)	545 (51.5%)	82 (49.4%)	28 (60.8%)
Baseline DMTs use, n (%)	658 (62.2%)	96 (57.8%)	41 (89.1%)

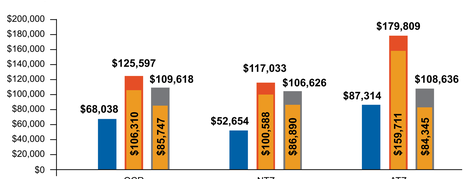
ATZ: alemtuzumab; MS: multiple sclerosis; NTZ: natalizumab; OCR: ocrelizumab; SD: standard deviation.

- In the first year, the Food and Drug Administration (FDA) recommended dosing was completed by 77.5% of patients in the OCR cohort, 65.1% in the NTZ and 80.4% in the ATZ cohorts; in the second year, these proportions reduced to 61.6%, 49.4% and 72.7%, respectively.

Cost of MS care

- **Figure 2** presents the mean total costs of care for OCR, NTZ, and ATZ at baseline and at first and second year of follow–up. For all three cohorts, the costs of care increased substantially during 1st year. Variations in the dosing schedules for the IV DMTs especially OCR in the first and second year led to differences in the first– and second–year cost.

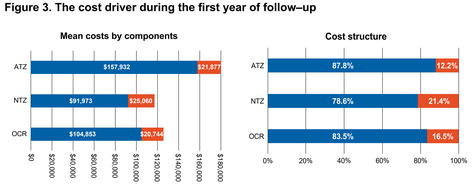
Figure 2. The mean total costs of care at baseline and first and second year of follow–up



Total cost is inclusive of inpatient cost, emergency department cost, outpatient cost, skilled nursing facility cost and pharmacy cost.

- Index drug costs was the main cost driver, accounting for more than 78% of the total costs of care in all three cohorts **(Figure 3).**

Figure 3. The cost driver during the first year of follow–up



Others include cost due to inpatient visit, outpatient visit, pharmacy, emergency department visit, physician office visit, laboratory test, skilled nursing facility and infusion cost.

- The average annual costs for OCR drug and administration calculated via WAC (based on Redbook) and infusion cost (via physician fee schedule) was $67,959, for NTZ was $104,490, and for ATZ was $130,384.
- **Table 3** presents the baseline and post–index healthcare costs including the breakdown of these costs across the three cohorts.

Table 3. MS cost of care[1]

	OCR (n=1,058)	NTZ (n=166)	ATZ (n=45)[2]
No. of patients completed the first–year dosing schedule, n (%)	820 (77.5)	108 (65.1)	36 (78.2)
Total cost[3] at baseline, mean (SD)	$68,038 ($52,079)	$52,654 ($43,217)	$87,314 ($51,423)
Medical cost, at baseline mean (SD)			
Inpatient cost	$4,267 ($20,067)	$6,470 ($21,727)	$1,568 ($5,813)
Outpatient cost	$30,363 ($42,150)	$10,667 ($11,267)	$33,634 ($51,539)
Pharmacy cost	$32,255 ($34,868)	$34,027 ($35,668)	$51,161 ($32,679)
Other cost[4]	$884 ($2,643)	$971 ($2,037)	$770 ($1,512)
Post index first year total cost, mean (SD)	$125,597 ($72,274)	$117,033 ($57,102)	$179,809 ($97,530)
Post index first year medical cost, mean (SD)			
Inpatient cost	$2,685 ($12,976)	$3,177 ($16,731)	$4,584 ($13,191)
Outpatient cost	$114,892 ($68,406)	$103,572 ($57,173)	$145,951 ($106,343)
Pharmacy cost	$7,119 ($15,189)	$9,188 ($20,087)	$27,631 ($52,970)
Other cost[4]	$705 ($1,797)	$805 ($2,080)	$838 ($2,659)
Index drug cost[5], mean (SD)	$104,853 ($66,927)	$91,973 ($51,373)	$157,932 ($93,374)
Index drug + infusion cost[4], mean (SD)	$106,310 ($66,818)	$100,588 ($50,805)	$159,711 ($95,322)
No. of patients with two years of follow–up, n (%)	526 (49.7)	77 (46.4)	22 (47.8)
No. of the patients completed first– and second–year dosing schedule[6], n (%)	324 (61.6)	38 (49.4)	16 (72.7)
Post index second year total cost, mean (SD)	$109,618 ($75,085)	$106,626 ($54,872)	$108,636 ($77,973)
Post index second year medical cost, mean (SD)			
Inpatient cost	$5,724 ($25,772)	$3,181 ($10,626)	$9,796 ($45,946)
Outpatient cost	$94,964 ($66,733)	$94,841 ($54,371)	$82,303 ($65,868)
Pharmacy cost	$7,748 ($14,472)	$8,179 ($16,175)	$15,788 ($27,058)
Other cost[4]	$786 ($3,511)	$608 ($911)	$775 ($1,430)
Index drug cost[5], mean (SD)	$82,399 ($63,649)	$71,427 ($53,378)	$73,619 ($66,381)
Index drug + infusion cost[5], mean (SD)	$85,747 ($65,088)	$86,890 ($53,585)	$84,345 ($63,935)

[1]Cost adjusted to 2019 dollars.
[2]One patient was removed due to incomplete cost data.
[3]Total cost is inclusive of inpatient cost, emergency department cost, outpatient cost, skilled nursing facility cost and pharmacy cost.
[4]Includes emergency department cost, physician office, laboratory test, and skilled nursing facility.
[5]Includes both from medical and pharmacy.
[6]Completers were defined as – OCR: receiving ≥3 doses within the first year (including index dose), ≥2 doses within the second year; NTZ: Receiving ≥12 doses within the first year (including index dose), ≥12 doses within the second year; ATZ: Receiving ≥5 doses within the first year (including index dose), 3 daily doses after 12 months.
ATZ: alemtuzumab; DMT: disease-modifying therapies; MS: multiple sclerosis; NTZ: natalizumab; OCR: ocrelizumab; SD: standard deviation.

Pre–Post cost analysis

- The mean total annual cost of care for the patients with prior exposure to DMT is drastically higher compared with DMT naive patients **(Table 4).**

Table 4. Pre–Post ocrelizumab cost differential

	DMT-Naive			DMT-exposed			Total		
	OCR	NTZ	ATZ	OCR	NTZ	ATZ	OCR	NTZ	ATZ
All cause total cost one year before DMT initiation									
n (%)	400 (38%)	70 (42%)	<10	**658 (62%)**	**96 (58%)**	**41 (89%)**	1,058	166	46
Mean (SD)	$33,858 ($37,141)	$21,564 ($33,610)	NC	**$88,817 ($48,806)**	**$75,324 ($34,524)**	**$94,199 ($49,298)**	$68,038 ($52,079)	$52,654 ($43,217)	$87,314 ($51,423)
All cause total first year cost after DMT initiation									
Mean (SD)	$120,494 ($67,428)	$112,184 ($56,551)	NC	**$128,700 ($74,947)**	**$120,569 ($57,537)**	**$188,356 ($97,397)**	$125,597 ($72,274)	$117,033 ($57,102)	$179,809 ($97,530)

ATZ: alemtuzumab; DMT: disease–modifying therapies; NC: not calculated due to very small sample size; NTZ: natalizumab; OCR: ocrelizumab.

Cost by site of care

- The hospital outpatient setting was the most common and most expensive site of infusion among patients on OCR **(Table 5).**

Table 5. Mean (SD) total healthcare cost by the site of care

	Consistent hospital outpatient			Consistent physician office			Consistent home setting		
	OCR	NTZ	ATZ	OCR	NTZ	ATZ	OCR	NTZ	ATZ
n (%)	617 (58%)	59 (37%)	22 (49%)	297 (28%)	65 (40%)	16 (36%)	31 (2.9%)	14 (9%)	<10
Baseline	$68,884 ($52,616)	$47,379 ($36,128)	$100,618 ($60,011)	$63,242 ($44,556)	$56,656 ($41,235)	$76,112 ($38,207)	$84,306 ($66,427)	$50,358 ($67,990)	NC
First year follow-up	$135,992 ($82,244)	$146,077 ($72,028)	$211,124 ($120,016)	$105,500 ($42,207)	$101,171 ($39,365)	$158,532 ($60,852)	$94,645 ($31,708)	$92,578 ($28,203)	NC
Second year follow-up	$117,192 ($83,469)	$128,690 ($69,839)	NC	$92,382 ($48,316)	$106,035 ($45,426)	NC	$78,345 ($37,966)	NC	NC

ATZ: alemtuzumab; NC: not calculated due to very small sample size; NTZ: natalizumab; OCR: ocrelizumab.

- The most common site of infusion among NTZ cohort was physician office, and hospital outpatient among ATZ.
- Proportion of outpatient hospital calculated as per site of care decreased over time, however it still accounted for over half of the OCR use settings.

Limitations

- For all the cost analysis due to new regulatory change and requirement, health plan allowed amount was used, instead of actual paid amount.
  - While this might not be the actual paid costs, the allowed amount is often equal to the final adjudicated paid amount in most cases in the HIRD® as it is the maximum amount a plan would pay for a covered health care service.
- As with any research using administrative data, medical care coding errors or omission may have occurred.
- The study was limited to commercially insured health plan members, and thus, results may not be generalizable to government–sponsored health insurance members or those uninsured or underinsured who may not have access to the healthcare resources of interest.

Conclusion

- Real–world IV treatment and medical costs for commercially insured patients were higher than the drug costs based on WAC and administration costs based on physician–fee schedules. Information on real–world costs of treatment is critical for more accurate estimation of costs to US payers and considerations for treatment or coverage decisions.

References

1. Nicholas et al 2020; Journal of medical economics, 23(8): 885-893.

Disclosures

- **Chinmay Deshpande** is an employee of Novartis Pharmaceuticals Corporation.
- **Hiangkiat Tan, Nicole Gabler, and Kapil Rathi** are employees of HealthCore, which is a consultancy whose activities on research projects are funded by various life sciences companies and health plans.
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