Burden of Illness and Healthcare Resource Utilisation Among Patients Newly Diagnosed with Amyotrophic Lateral Sclerosis in the United States: A Retrospective, Observational, Cohort Design Study

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OBJECTIVE

To understand the burden of illness, healthcare resource utilisation (HCRU), and healthcare costs (HCCs) among patients newly diagnosed with Amyotrophic lateral sclerosis (ALS), who are covered under commercial insurance and Medicare Advantage in the United States (US)

BACKGROUND

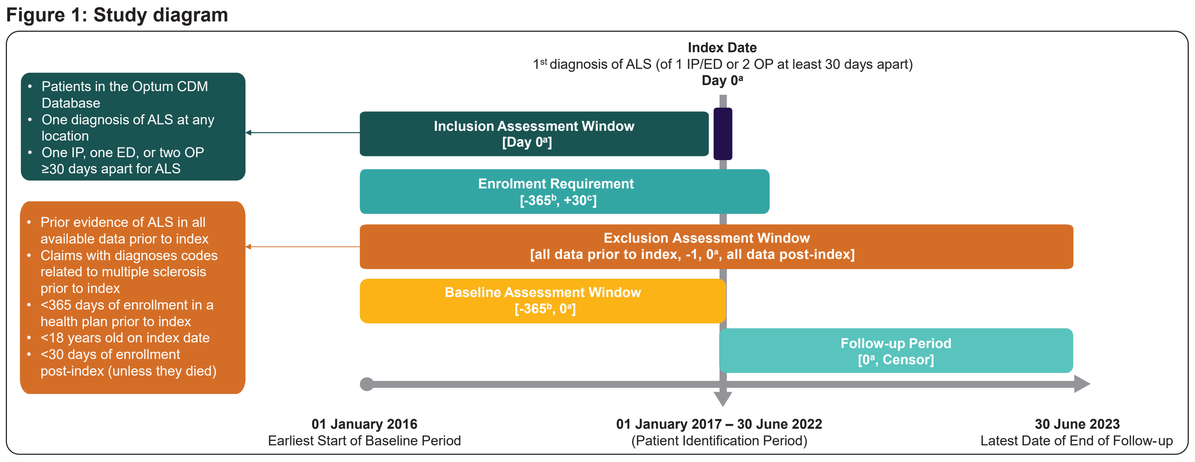
- ALS is a neurogenerative, progressive motor neuron disease that results in paralysis and ultimately leads to death from respiratory failure within 3 to 5 years following diagnosis[1]
- According to the National ALS Registry, in the US, prevalence of ALS for the year 2025 is estimated at ~10.1 cases per 100,000[2]
- Currently, there is no cure for ALS, and contemporary treatments focus on slowing the rate of disease progression and improving the quality of life in affected patients[3]
- Data specifically on the clinical and economic burden in patients newly diagnosed with ALS in the US is limited

METHODS

Study design and population

- This retrospective, observational, cohort study utilised secondary data from the Optum Clinformatics® claims database (an administrative claims database linked to date of death) from 01 January 2016 to 30 June 2023 (**Figure 1**)
- Adult patients newly diagnosed with ALS, who had ≥12 months of baseline health plan enrolment and ≥30 days of follow-up enrolment, were identified between 01 January 2017 and 30 June 2022 (**Figure 1**)
- The index date was defined as the date of the first observed claim (one inpatient claim, or one emergency department [ED], or 2 outpatient claims ≥30 days apart) with diagnosis for ALS (International Classification of Diseases, 10th Revision [ICD-10] G12.21) in any position
- For the present analysis, patients with ALS were identified as per the inclusion/exclusion criteria depicted in (**Figure 2**)

Figure 1: Study diagram



ALS, amyotrophic lateral sclerosis; ED, emergency department visit; IP, inpatient visit; OP, outpatient visit. [a]Index date defined as the date of the first observed claim (one IP claim, or one ED, or 2 OP claims ≥30 days apart) with diagnosis for ALS (ICD-10 G12.21) in any position; [b]365 days prior through index; [c]30 days after index.

Study measures

- Patients' demographics were assessed on the index date, comorbidities were assessed over 1-year baseline period, and HCRU and HCCs were assessed at baseline and over follow-up
  - HCRU included all-cause hospitalisations, intensive care unit (ICU) admissions, ED visits, non-ED outpatient visits and specialists' visits
  - HCCs were reported as mean±standard deviation (SD) and median (interquartile range [IQR]) cost per patient per month (PPPM) at baseline and at follow-up
    - HCCs calculation included total costs, which comprised of all-cause hospitalisations, ICU admissions, ED visits, outpatient visits, and pharmacy costs

Statistical analysis

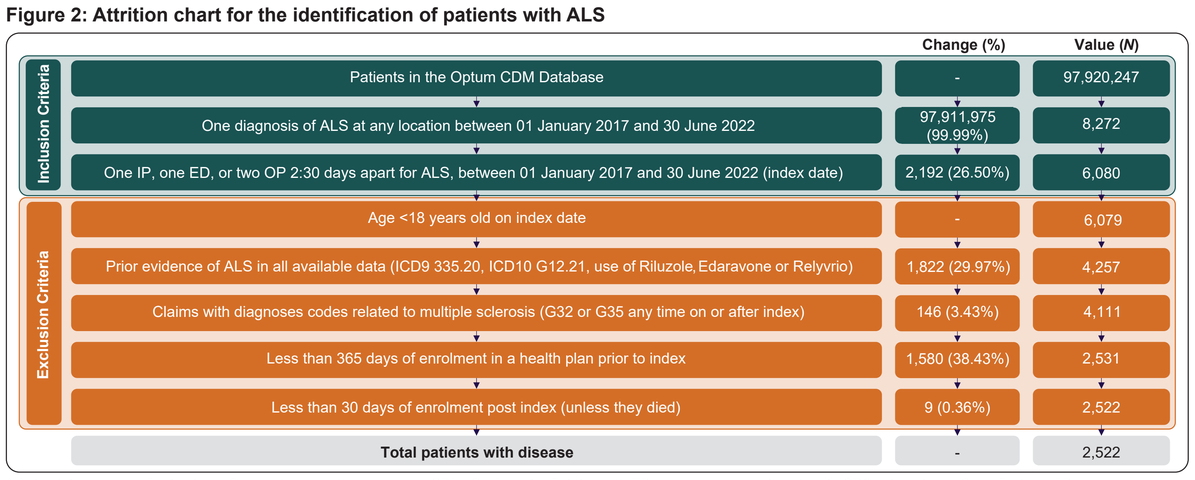
- All study variables were analysed using descriptive statistics, and did not include comparisons between groups
- All HCCs were reported in US dollars, adjusted to Year 2022 values

RESULTS

Baseline demographics

- Of the 2,522 patients identified (**Figure 2**) (75% aged ≥65 years at diagnosis; 55% male), 567 had commercial insurance (50% aged 55–64 years; 61% male), whereas 1,954 had Medicare Advantage (92% aged ≥65 years; 54% male) (**Table 1**)

Figure 2: Attrition chart for the identification of patients with ALS



N is the total number of patients. ALS, amyotrophic lateral sclerosis; CDM, Clinformatics® Data Mart; ED, emergency department visit; ICD9, International Classification of Diseases, 9th Revision; ICD10, International Classification of Diseases, 10th Revision; IP, inpatient visit, OP, outpatient visit.

Table 1: Baseline demographics assessed at cohort entry date

Baseline demographics	Overall patient population (*N*=2,522)	Commercial insurance only (*N*=567)	Medicare Advantage only (*N*=1,954)
Age categories, years, *n* (%)			
18–55	220 (9)	180 (32)	40 (2)
55–64	403 (16)	281 (50)	122 (6)
≥65	1,899 (75)	106 (19)	1,792 (92)
Gender, *n* (%)			
Male	1,391 (55)	344 (61)	1,046 (54)
Female	1,127 (45)	219 (39)	908 (47)
Missing	4 (0.2)	4 (1)	0 (0)
Race, *n* (%)			
Black	207 (8)	44 (8)	163 (8)
Asian	57 (2)	12 (2)	45 (2)
White	1,909 (76)	436 (77)	1,472 (75)
Hispanic	208 (8)	46 (8)	162 (8)
Other/Unknown	141 (6)	29 (5)	112 (6)
Region, *n* (%)			
Northeast	370 (15)	77 (14)	293 (15)
Midwest	555 (22)	169 (30)	386 (20)
South	1,104 (44)	246 (43)	858 (44)
West	486 (19)	70 (12)	416 (21)
Other/Unknown	8 (0.3)	5 (1)	2 (0.1)
Year of cohort entry, *n* (%)			
2017	426 (17)	103 (18)	322 (17)
2018	478 (19)	135 (24)	343 (18)
2019	448 (18)	97 (17)	351 (18)
2020	448 (18)	96 (17)	352 (18)
2021	489 (19)	94 (17)	395 (20)
2022	233 (9)	42 (7)	191 (10)

N is the total number of patients. *n* is the subset of patients.

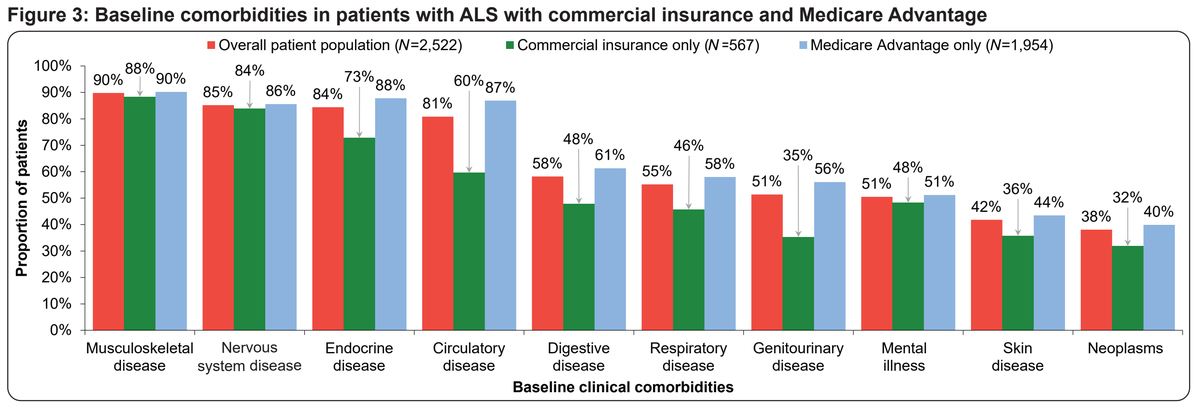
Clinical comorbidities

- At baseline, the most common comorbidities in the overall patient population were musculoskeletal conditions (90% [*n*=2,265]), nervous system disorders (85% [*n*=2,149]), endocrine disorders (84% [*n*=2,129]), and circulatory diseases (81% [*n*=2,037]) (**Figure 3**)

Conclusions

This retrospective, observational, cohort design study highlights the significant clinical and economic burden of ALS in the US. The clinical burden in patients with ALS is characterised by high prevalence of comorbidity (~≥80%), and the economic burden is marked by a substantial increase in HCRU post-diagnosis, and a nearly three-fold increase in monthly HCCs

Figure 3: Baseline comorbidities in patients with ALS with commercial insurance and Medicare Advantage

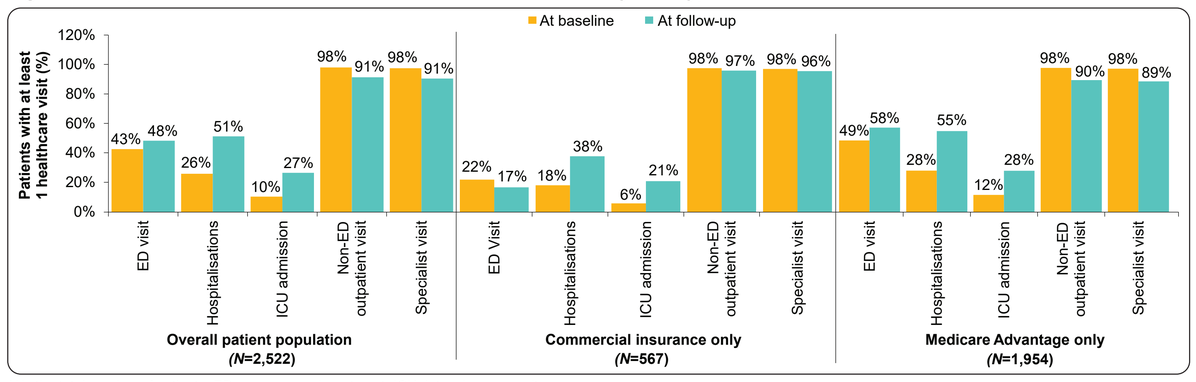


N is the total number of patients. ALS, amyotrophic lateral sclerosis.

Healthcare resource utilisation

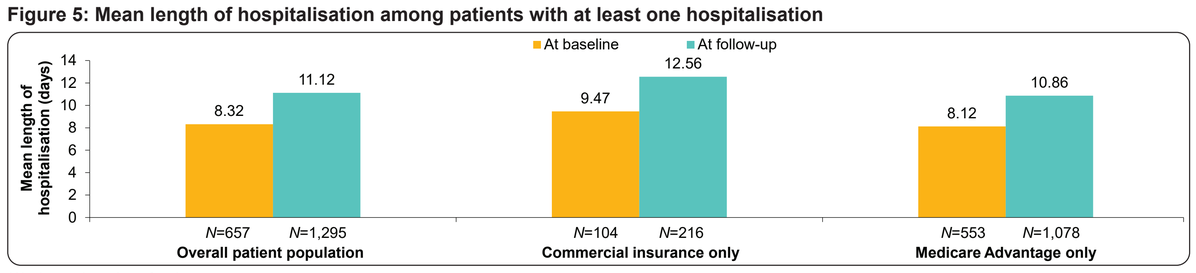
- In the overall patient population and among the subgroup of Medicare Advantage patients, there was an increase in proportion of patients with hospitalisation, ICU admissions and ED visits from the baseline to follow-up. Conversely, there was a decrease in the proportion of patients with at least 1 specialist visit and non-ED outpatient visits (**Figure 4**). Trends were consistent for the subgroup of patients covered under commercial insurance, other than a decrease in ED visits
- Among patients with at least one hospitalisation, the mean±SD length of hospitalisation for the overall population increased from 8.32±10.14 days at baseline to 11.12±17.40 days at follow-up (**Figure 5**)
  - A similar trend was also observed for commercially insured patients and in patients with Medicare Advantage

Figure 4: Proportion of patients with at least one healthcare visit by visit type



N is the total number of patients. ED, emergency department; ICU, intensive care unit.

Figure 5: Mean length of hospitalisation among patients with at least one hospitalisation



N is the total number of patients.

Healthcare costs

- In the overall patient population, the mean total costs (medical services and pharmacy) PPPM increased from $4,394 at baseline to $14,408 over a follow-up duration of 1.4 years (**Table 2**)
  - This increase in mean costs PPPM was primarily driven by all-cause hospitalisations ($1,886 to $9,306), ICU admissions ($307 to $2,676), and non-ED outpatient cases ($1,421 to $1,767). Similar trends were observed for patient covered under commercial insurance and Medicare Advantage

Table 2: Healthcare costs in the overall patient population of ALS, in patients covered under commercial insurance and in patients covered under Medicare Advantage

Healthcare costs	Overall patient population (*N*=2,522)		Commercial insurance only (*N*=567)		Medicare Advantage only (*N*=1,954)	
	At baseline (12 months)	At follow-up	At baseline (12 months)	At follow-up	At baseline (12 months)	At follow-up
Follow-up, years, mean±SD	-	1.4±1.3	-	1.4±1.2	-	1.4±1.3
Total costs, PPPM [medical services + pharmacy]						
Patients with any cost[a], *n* (%)	2,506 (99)	2,521 (100)	563 (99)	567 (100)	1,942 (99)	1,953 (100)
Mean±SD	$4,394±$7,733	$14,408±$32,467	$3,388±$7,033	$10,877±$21,443	$4,688±$7,904	$15,425±$34,966
Median [IQR]	$1,750 [$831–$4,613]	$4,926 [$1,879 $14,025]	$1,271 [$594–$2,591]	$3,964 [$1,451–$11,247]	$1,941 [$937–$5,267]	$5,211 [$2,029–$14,641]
Any hospitalisation costs, PPPM						
Patients with any cost[a], *n* (%)	656 (26)	1,294 (51)	104 (18)	216 (38)	552 (28)	1,077 (55)
Mean±SD	$1,886±$6,123	$9,307±$30,682	$1,393±$5,415	$5,551±$19,518	$2,030±$6,309	$10,399±$33,158
Median [IQR]	$0 [$0–$305]	$114 [$0–$5,157]	$0 [$0–$0]	$0 [$0–$2,126]	$0 [$0–$1,154]	$668 [$0–$6,126]
ICU costs, PPPM						
Patients with any cost[a], *n* (%)	178 (7)	469 (19)	29 (5)	108 (19)	149 (8)	361 (19)
Mean±SD	$307±$2,090	$2,676±$15,201	$151±$937	$1,969±$11,793	$352±$2,319	$2,883±$16,055
Median [IQR]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]
Long-term care costs, PPPM						
Patients with any cost[a], *n* (%)	208 (8)	384 (15)	17 (3)	43 (8)	191 (10)	341 (18)
Mean±SD	$197±$850	$541±$2,225	$60±$389	$233±$1,437	$237±$939	$630±$2,399
Median [IQR]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$0]
Non-ED outpatient costs, PPPM						
Patients with any cost[a], *n* (%)	2,477 (98)	2,306 (91)	557 (98)	548 (97)	1,919 (98)	1,757 (90)
Mean±SD	$1,421±$1,948	$1,767±$4,954	$1,370±$2,038	$2,199±$5,520	$1,437±$1,922	$1,638±$4,774
Median [IQR]	$911 [$464–$1,651]	$792 [$332–$1,566]	$814 [$416–$1,535]	$999 [$502–$1,949]	$935 [$480–$1,683]	$728 [$280–$1,430]
ED costs, PPPM						
Patients with any cost[a], *n* (%)	1,079 (43)	1,220 (48)	126 (22)	96 (17)	953 (49)	1,130 (58)
Mean±SD	$349±$1,839	$517±$2,327	$50±$238	$79±$649	$436±$2,077	$647±$2,619
Median [IQR]	$0 [$0–$309]	$0 [$0–$359]	$0 [$0–$0]	$0 [$0–$0]	$0 [$0–$429]	$74 [$0–$539]
Other costs, PPPM						
Patients with any cost[a], *n* (%)	1,077 (43)	1,835 (73)	214 (38)	391 (69)	863 (44)	1,443 (74)
Mean±SD	$232±$1,619	$1,095±$2,338	$147±$843	$1,583±$3,446	$257±$1,782	$952±$1,874
Median [IQR]	$0 [$0–$107]	$321 [$0–$1,339]	$0 [$0–$48]	$248 [$0–$1,465]	$0 [$0–$136]	$337 [$0–$1,303]
Pharmacy costs, PPPM						
Patients with any cost[a], *n* (%)	2,208 (88)	2,140 (85)	516 (91)	528 (93)	1,691 (87)	1,611 (82)
Mean±SD	$318±$1,326	$819±$3,132	$302±$1,434	$940±$2,510	$322±$1,294	$777±$3,274
Median [IQR]	$50 [$11–$195]	$99 [$14–$413]	$32 [$7–$140]	$134 [$36–$567]	$57 [$12–$219]	$88 [$10–$369]

N is the total number of patients. *n* is the subset of patients. [a]Includes costs estimated among all patients with ≥1 HCRU of the respective category. ALS, amyotrophic lateral sclerosis; ED, emergency department; HCRU, healthcare resource utilisation; ICU, intensive care unit; IQR, interquartile range; PPPM, per patient per month; SD, standard deviation.

LIMITATIONS

- As the administrative claims database includes transactional data submitted for reimbursement of services, some misclassification of patients may have occurred, including that of the inclusion and exclusion criteria as well as comorbidities
- Given the limited observability of patients in claims databases, certain prevalent patients may have been misclassified as newly diagnosed or incident patients, thus underestimating the time between disease progression milestones
- Uninsured medical devices and an inability to pay for assistive equipment could have resulted in a miscalculation of HCCs
- Assuming that HCRU was distributed homogeneously throughout the year, the overall HCRU and cost PPPM may have been overestimated or underestimated for patients with shorter observability

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DISCLOSURES

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