Demographic and Clinical Characteristics in Amyotrophic Lateral Sclerosis Patients Treated With IV Edaravone: Results From a US Administrative Claims Database

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BACKGROUND

- Currently, 2 treatments for amyotrophic lateral sclerosis (ALS) are approved by the US Food and Drug Administration: riluzole, approved in 1995, and IV edaravone, approved in 2017
- In the pivotal clinical trial, IV edaravone was shown to slow down the loss of functional decline by 33% (*P*=.0013) at 24 weeks, compared with placebo, as measured by scores on the ALS Functional Rating Scale-Revised (ALSFRS-R)[1]
- Real-world evidence is useful across a product's lifecycle, as it can provide insights into such aspects as epidemiology, treatment effectiveness, and health economic value and impact
- Studies describing the real-world effectiveness of IV edaravone are limited

HYPOTHESIS

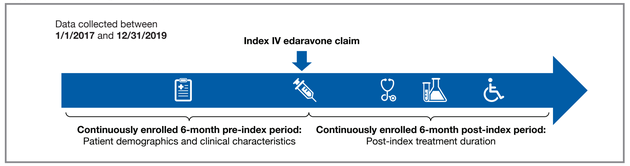
- Data from a US administrative claims database may help provide real-world evidence on the use of IV edaravone for the treatment of ALS

METHODS

Data source

- Optum's Clinformatics®Data Mart (CDM) is a statistically de-identified database of administrative health claims spanning all 50 states for members with commercial and Medicare Advantage insurance[2]
- This is a closed system with '360 degree' view of a patient as demonstrated by the administrative, payer claims, including patient enrollment information, patient demographics, mortality information, physician information, facility claims, pharmacy claims, inpatient hospital claims, outpatient hospital claims, emergency room visits, physician's office visits, surgery center claims, and lab results
- The current analysis includes commercially insured ALS patients who initiated treatment with IV edaravone between August 8, 2017 and June 30, 2019 (index IV edaravone claim), and who had 6 months of continuous enrollment both pre- and post-index IV edaravone claim (**Figure 1**)

Figure 1. Study design



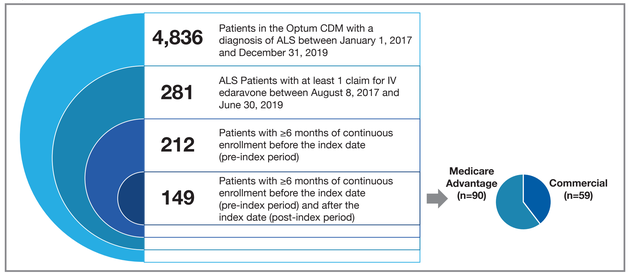
Key inclusion criteria

1. Adults ≥18 years of age on the index IV edaravone date
2. Diagnosis of ALS within 6 months prior to the index date
   - This was indicated by a diagnosis with the International Classification of Diseases codes ICD-10-CM code G12.21, ICD-9-CM: 335.20 on any claim in any setting (outpatient or inpatient)
3. Initiated IV edaravone within 6 months of ALS diagnosis between August 8, 2017 and June 30, 2019
   - This was indicated by a claim for IV edaravone using HCPCS codes (J1301, J3490, C9493) or NDC codes (70510-2171-xx)
4. 6 months of continuous enrollment in the commercial database pre- and post-index IV edaravone claim

RESULTS

- A total of 149 patients were included in the analysis (**Figure 2**)
- Mean age was 64.4 years (SD: 10.3); 85 (57.0%) were male; 59 (39.6%) were covered by commercial insurance and 90 (60.4%) were covered by Medicare Advantage plans. IV edaravone was initiated at home among 91 (61.7%) patients, in an outpatient facility among 57 (38.3%) patients, and at an unspecified site in 1 patient (**Table 1**)

Figure 2. ALS patient selection process



IV edaravone patient counts

- 281 ALS patients had at least 1 claim for IV edaravone
- 149 had at least 6 months of pre-index and post-index continuous enrollment in the database[a] (**Figure 3**)
  - 59 (39.6%) were covered by commercial plans
  - 90 (60.4%) were covered by Medicare Advantage

[a]The start date of IV edaravone is defined as the index date.

Figure 3. Number of IV edaravone patients by year of enrollment and by insurance coverage

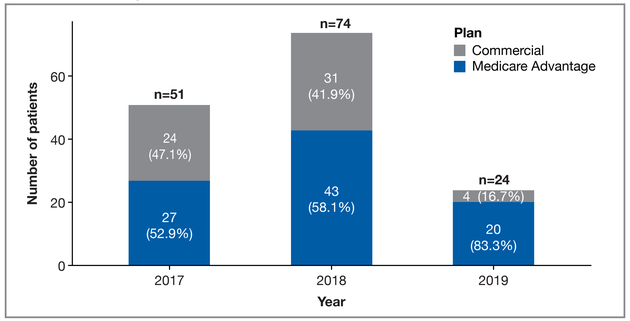


Table 1. Demographic characteristics in ALS patients* treated with IV edaravone

	Commercial	Medicare Advantage	Total
N (%)	59 (39.6)	90 (60.4)	149 (100)
Gender, n (%)			
Male	37 (62.7)	48 (53.3)	85 (57.0)
Age group, n (%), years			
18 – 39	2 (3.4)	0 (0.0)	2 (1.3)
40 – 49	11 (18.6)	2 (2.2)	13 (8.7)
50 – 59	21 (35.6)	8 (8.9)	29 (19.5)
60 – 69	22 (37.3)	30 (33.3)	52 (34.9)
70 – 79	3 (5.1)	45 (50.0)	48 (32.2)
80+	0 (0.0)	5 (5.6)	5 (3.4)
Age (mean, SD), years	56.7 (8.5)	69.5 (7.9)	64.4 (10.3)
Race, n (%)			
White	50 (84.7)	53 (58.9)	103 (69.1)
Other	6 (10.2)	16 (17.8)	22 (14.8)
Unknown	3 (5.1)	21 (23.3)	24 (16.1)
Facility, n (%)	23 (39.7)	34 (37.8)	57 (38.5)
Home, n (%)	35 (60.3)	56 (62.2)	91 (61.5)
Region, n (%)			
Midwest	22 (37.3)	20 (22.2)	42 (28.2)
Northeast	12 (20.3)	19 (21.1)	31 (20.8)
South	16 (27.1)	24 (26.7)	40 (26.8)
West	9 (15.3)	26 (28.9)	35 (23.5)
Unknown	0 (0.0)	1 (1.1)	1 (0.7)

*Patients with at least 6 months of pre-index and post-index continuous enrollment in the database.

- In the pre-index period, 10 (6.7%) and 45 (30.2%) patients had at least 1 claim for cardiovascular events and chronic pulmonary disease, respectively (**Table 2**)
- ALS-related diagnostic testing are shown for patients treated with IV edaravone (**Table 3**)
- In the total sample, median [IQR] treatment duration of IV edaravone was 307.0 [160.0, 470.0] days (**Figure 4**)
  - The shorter treatment duration for patients who are covered by Medicare Advantage may be due to their older age at start of treatment (Table 1) and transition into hospice care or death sooner than the commercial patients, resulting in shorter persistency of treatment

Table 2. Pre-index period comorbidities in ALS patients* treated with IV edaravone

	Commercial	Medicare Advantage	Total
N (%)	59 (39.6)	90 (60.4)	149 (100)
Myocardial infarction, n (%)	1 (1.7)	3 (3.3)	4 (2.7)
Congestive heart failure, n (%)	1 (1.7)	5 (5.6)	6 (4.0)
Dementia, n (%)	1 (1.7)	4 (4.4)	5 (3.4)
Chronic pulmonary disease, n (%)	20 (33.9)	25 (27.8)	45 (30.2)

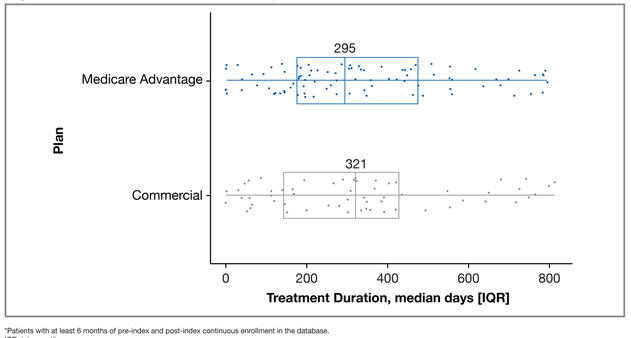
*Patients with at least 6 months of pre-index and post-index continuous enrollment in the database.

Table 3. Pre-index period ALS-related diagnostic testing in ALS patients* treated with IV edaravone

	Commercial	Medicare Advantage	Total
N (%)	59 (39.6)	90 (60.4)	149 (100)
Imaging	23 (39.0)	45 (50.0)	68 (45.6)
MRI	42 (71.2)	47 (52.2)	89 (59.7)
Nerve conduction studies / Electromyography	54 (91.5)	65 (72.2)	119 (79.9)
Muscle biopsy	1 (1.7)	1 (1.1)	2 (1.3)
Lumbar puncture	15 (25.4)	8 (8.9)	23 (15.4)
Creatinine kinase	47 (79.7)	53 (58.9)	100 (67.1)
Vitamin B12	47 (79.7)	60 (66.7)	107 (71.8)

*Patients with at least 6 months of pre-index and post-index continuous enrollment in the database.

Figure 4. Treatment duration in ALS patients* treated with IV edaravone



*Patients with at least 6 months of pre-index and post-index continuous enrollment in the database.
IQR=interquartile range.

LIMITATIONS

- This study was limited to only those individuals with commercial health coverage or Medicare Advantage plans. Consequently, results of this analysis may not be generalizable to ALS patients with other insurance plans or without health insurance coverage
- This study relied on administrative claims data, which are subject to coding limitations and entry error
- The possibility of under-diagnosis of ALS may have led to a selection bias and/or smaller sample sizes, as ALS patients who were untreated or who did not have a relevant diagnosis recorded on their medical claims were excluded
- Patients who no longer had health insurance or who died during the post-index period were excluded. Therefore, the study population may appear to have been healthier than the total population of ALS patients in the database

CONCLUSIONS

- This analysis provides a description of demographic and clinical characteristics and treatment duration in patients treated for ALS with IV edaravone and who were enrolled in an administrative claims database
- Future studies are needed to quantify time to real-world outcomes (eg, time to use of noninvasive/invasive ventilation)

REFERENCES

1. Writing Group; Edaravone (MCI-186) ALS 19 Study Group. *Lancet Neurol*. 2017;16(7):505-512.
2. Optum's de-identified Clinformatics® Data Mart Database (2007-2020).

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Disclosures
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