Treatment patterns of intravenous edaravone in patients with amyotrophic lateral sclerosis: A retrospective administrative claims analysis

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BACKGROUND

Amyotrophic lateral sclerosis (ALS) is an incurable and progressive neurodegenerative disease.[1-3] ALS pharmacotherapy has historically been limited.[4] Although intravenous (IV) edaravone has been on the market in the United States (US) since 2017, there are limited data on real-world IV edaravone treatment patterns.[5]

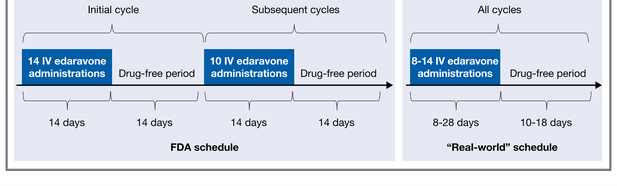
OBJECTIVES

To describe the treatment patterns of patients with ALS utilizing IV edaravone

METHODS

- Healthcare Integrated Research Database (HIRD®) is a geographically diverse repository of longitudinal medical and pharmacy claims data from Anthem-affiliated health plans, representing over 50 million lives across the US
- This retrospective observational study used the HIRD to identify patients with an ALS diagnosis between Jan 1, 2012, and Mar 31, 2022, who were treated with IV edaravone between Aug 8, 2017 (the first date of US market availability) and Mar 31, 2022
- Treatment patterns 12 months post-index (index date = first observed IV edaravone administration) were described and explored in 2 ways – a Food and Drug Administration (FDA)-approved dosing schedule and a more flexible schedule that accounted for real-world variability (**Figure 1**)
- Days covered included administration days and drug-free days in a cycle. Patients with ≥80% proportion of days covered over a year were considered adherent. Discontinuation was defined as ≥60 drug-free days outside of a cycle

Figure 1. IV edaravone cycles under FDA and "real-world" schedules



RESULTS

- Demographics for 110 IV edaravone–treated patients with ALS are presented in **Table 1**

Table 1. Patient demographics

	IV Edaravone Users
Number of patients, N	110
Sex, n (%)	
Female	42 (38)
Male	68 (62)
Age, years	
Mean (SD)	58.0 (11.3)
Median (IQR)	58.5 (53-64)
Age categories, n (%)	
<45 years	10 (9)
45-54 years	22 (20)
55-64 years	52 (47)
65-74 years	17 (15)
≥75 years	9 (8)
Health plan type, n (%)	
HMO	19 (17)
PPO	78 (71)
CDHP	13 (12)
Payor, n (%)	
Commercial	95 (86)
Medicare Advantage/Supplemental	15 (14)
Geographic region, n (%)	
Northeast	12 (11)
Midwest	17 (15)
South	31 (28)
West	45 (41)
Unknown	5 (5)

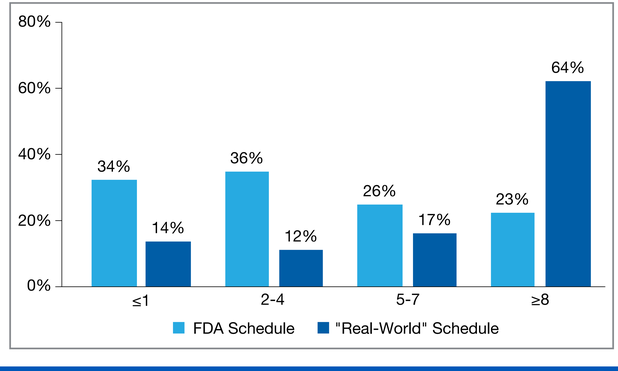
CDHP, consumer-directed health plan; HMO, health maintenance organization; IQR, interquartile range; PPO, preferred provider organization.

- More patients were considered adherent to the "real-world" schedule (54%) than the FDA schedule (16%) (**Table 2**), with patients completing a mean of 8.1 cycles under the "real-world" schedule and 3.9 cycles under the FDA schedule (**Figure 2**)
- Under both schedules, 25% of patients discontinued treatment after a mean of 118.8 days (SD = 92.4)

Table 2. Treatment patterns in 110 eligible patients over the 12-month post-index period

Treatment Patterns	FDA Schedule	"Real-World" Schedule
Number of days covered, mean (SD)	180.9 (93.3)	250.0 (109.7)
Proportion of days covered in %, mean (SD)	50.0 (26.0)	69.0 (30.0)
Adherent, n (%)	16 (16)	59 (54)
Number of cycles completed, mean (SD)	3.9 (3.6)	8.1 (4.5)

Figure 2. Number of cycles completed during 12-month post-index period



CONCLUSIONS

- Only a minority of patients followed the FDA-approved schedule for IV edaravone
- Real-world utilization varied from the approved schedule. While there may be clinical reasons for variability in use, there is an opportunity to improve adherence in general
- Lack of adherence may limit the maximum potential benefit from any treatment

LIMITATIONS

- Claims are primarily collected for billing and reimbursement purposes and may be subject to coding biases, inconsistencies, and missing data leading to misclassification and measurement error
- All patients in this study were enrolled in commercial or Medicare Advantage health plans in the US and satisfied all selection criteria. The results may not be generalizable to patients with other types of health insurance, the uninsured, or those outside the US

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