#HPR105

Impact of Social Determinants of Health on Access to Device Aided Therapy Services for Medicare Fee-for-Service Beneficiaries with Advanced Parkinson's Disease

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Background

- The prevalence of Parkinson's Disease (PD), a slowly progressive neurodegenerative disorder, among adults ages 45 and older in the United States (U.S.) was estimated to be approximately 1 million people in 2020, growing to 1.2 million in 2030.[1,2]
- Levodopa/carbidopa remains the gold-standard oral medication to treat the symptoms of PD.
- However, the effect of oral levodopa/carbidopa may wane over time as disease advances, requiring patients to take more pills, leading to complex medication regimens that impact quality of life and adherence to treatment.[3]
- Patients uncontrolled on oral medications may be eligible for Device Aided Therapies (DATs). Two surgical DATs are available in the U.S.:
  - Carbidopa/levodopa enteral suspension (CLES) is a surgical intervention in which a percutaneous endoscopic gastrostomy with jejunal tube is placed in the wall of the stomach to permit continuous 16-hour delivery of carbidopa/levodopa, via an external portable pump, into the small intestine where it is most absorbed.[4]
  - Deep Brain Stimulation (DBS) requires two surgeries: The first to place electrode(s) in the brain and the second to implant the neurostimulator under the skin on the chest.[5]
- Despite efficacy of surgical DATs to manage PD symptoms and improve quality of life, patient access to these treatments may be limited due to social determinants of health (SDOH).
- According to the World Health Organization, SDOH are the conditions in which people are born, grow, work, live, and age.
  - There is growing evidence SDOH have a powerful impact on health outcomes and access to care.
- No studies to our knowledge have assessed how SDOH impact patient access to DAT.

Objective

- To examine advanced Parkinson's disease (APD) patient characteristics and SDOH on receipt of DAT in the U.S. from 2018-2020 .

Data Sources

- The 100% Medicare Fee-for-Service (FFS) Parts A/B medical claims and Part D Prescription Drug Event data from 1/1/2018 through 12/31/2020 were utilized for the analysis.
- Acxiom Info Base Geo© files 2017-2020 were utilized to capture SDOH variables at the near-neighborhood level based on patient's ZIP-code.

Methods

- Demographic characteristics were assessed on index.
  - For DAT patients, the index date was the first date either CLES or DBS was initiated.
  - For non-DAT patients, the index date was calculated as the APD date plus the average number of days between APD diagnosis date and DAT initiation.
- Clinical characteristics, SDOH, and healthcare resource utilization were assessed during the 12-month baseline period.
- Receipt of any DAT (CLES or DBS) was assessed during the 12 months following the APD diagnosis date.
- Demographics and clinical characteristics included were presented via means, medians, and standard deviations (SD) for continuous variables, and frequencies and proportions for categorical variables.
- Statistically significant differences across study groups (any DAT vs. non-DAT) were determined via analysis of variance (ANOVA) for normally distributed continuous variables, Kruskal-Wallis test for skewed variables, and Chi-square tests of equality of proportions for categorical variables.

Results

- Among 503,245 Medicare beneficiaries with PD, 112,773 (22%) were APD. (Figure 1)
- 2.17% of APD patients received a DAT across 416 facilities.
- DAT recipients were younger and more often male than those who did not receive DAT. (Table 1)
- SDOH characteristics impacted the likelihood of receiving DAT. (Table 1, Table 3, Figure 2)
- DAT recipients had:
  - A lower Charlson Comorbidity Index (CCI) score compared to patients that did not receive DAT. (1.7 vs. 2.6; p<0.01)
  - Fewer comorbidities, including hypertension, hyperlipidemia, anemia, diabetes, ischemic heart disease, chronic kidney disease, acquired hypothyroidism, and dementia. (p<0.0001)
  - Higher average levodopa equivalent daily dose (mg) (1,088 vs. 759; p<0.0001). (Table 2)
- Patients that received DAT were:
  - Less likely to have a baseline hospitalization. (22.1% vs. 24.4%; p<0.0001)
  - More likely to see certain specialists including visits to neurologists, neurosurgeons, gastroenterologists, and psychiatrists compared to patients that did not receive DAT (p<0.0001). (Table 4)

Figure 1. Study Population Attrition

≥1 inpatient or ≥2 outpatient claims with a diagnosis of PD, January 1, 2018 – December 31, 2020
N=503,245

APD diagnosis date: First date patient met any of the APD diagnosis criteria, following PD diagnosis date, January 1, 2018 – December 31, 2020
N=183,168

APD diagnosis criteria:

LEDD >1000mg[1]	≥5 levodopa-containing pills/day[2]	Non-oral treatments[3]	Rescue medication[4]	Dyskinesia[5]
N=46,362	**N=115,981**	**N=9,800**	**N=733**	**N=10,292**

DAT: Received CLES or DBS within 12 months of APD diagnosis date
Date of DAT or calculated date = index
N who received DAT=3,221 N who did not receive DAT=179,947

≥18 years of age as of the index date
N=174,373

Patients with select diagnoses[6] at any time during the pre-index period were excluded
N=157,592

Continuous enrollment in medical and pharmacy benefits for ≥12 months pre- and post-index
N=112,773

APD patients who received DAT	APD patients who did not receive DAT
N=2,457	N=110,323

1. Levodopa equivalent daily dose of >1000mg of ≥1 oral PD medication over a 30-day consecutive period
2. Average of ≥5 levodopa-containing pills per day over a 30-day consecutive period
3. Presence of any non-oral treatments (DBS, CLES, rotigotine transdermal system)
4. Presence of any rescue medication (apomorphine hydrochloride SC injection, sublingual apomorphine tablets, levodopa inhalation)
5. Presence of dyskinesia diagnosis or anti-dyskinetic medication (amantadine)
6. Secondary parkinsonism or other degenerative diseases of the basal ganglia

APD: advanced Parkinson's disease; CLES: carbidopa/levodopa enteral suspension; DAT: device-aided therapy; DBS: deep brain stimulation; LEDD: levodopa equivalent daily dose; PD: Parkinson's disease

Figure 2. Relationship Between Select SDOH Characteristics and Receipt of DAT

Race/Ethnicity
Black Patients
3.1x less likely
to receive DAT vs. White patients

Income
Dual Eligible
2.1x less likely
to receive DAT

Disability
Disabled
1.8x more likely
to receive DAT

Education
High School or Less
1.03x less likely
to receive DAT

Vehicle
No Vehicle
1.1x less likely
to receive DAT

DAT: device-aided therapy; SDOH: social determinants of health

Conclusion

- We found disparities in likelihood of receiving DAT based on several SDOH factors.
- Patients with DAT were more likely than non-DAT patients to be younger, White, have higher household income, higher education, be married, and own a vehicle.
- These disparities may affect access to treatment for patients with advanced PD who may benefit from DAT.

Table 1. Patient Characteristics

	APD Patients Who Received Any DAT	APD Patients Who Did Not Receive DAT	P-Value DAT vs. No DAT
Unique Number of Patients	2,450	110,323	
Patient Age at Index Date in Years			
Mean (Median)	70.9 (71.2)	76.2 (76.3)	<0.0001
Gender			
Male	2.4%	97.6%	<0.0001
Female	1.8%	98.2%	
Race/Ethnicity			
White	2.2%	97.8%	<0.0001
Black	0.7%	99.3%	
Asian	1.9%	98.1%	
Hispanic	2.7%	97.3%	
Other Race	2.7%	97.3%	
Unknown	4.0%	96.0%	
Dual Eligible Status			
Dual	1.2%	98.8%	<0.0001
Non-Dual	2.4%	97.6%	
Original Reason for Medicare Entitlement			
Age	1.9%	98.1%	<0.0001
Disability and/or ESRD	3.4%	96.6%	
Urban/Rural Indicator			
Urban	2.2%	97.8%	0.8582
Rural	2.2%	97.8%	

APD: advanced Parkinson's disease; DAT: device-aided therapy; ESRD: end stage renal disease

Table 2. Clinical Characteristics

	APD Patients Who Received Any DAT	APD Patients Who Did Not Receive DAT	P-Value DAT vs. No DAT
Unique Number of Patients	2,450	110,323	
CCI Score (Mean, SD)	1.7 (1.9)	2.6 (2.6)	<.0001
10 Most Prevalent Comorbidities			
Hypertension	61.5%	73.3%	<0.0001
Hyperlipidemia	57.3%	61.1%	0.0001
Rheumatoid Arthritis/ Osteoarthritis	46.3%	47.9%	0.1248
Depression	39.1%	36.4%	0.0050
Anemia	21.6%	30.1%	<0.0001
Diabetes	20.7%	29.0%	<0.0001
Ischemic Heart Disease	22.8%	28.7%	<0.0001
Chronic Kidney Disease	17.6%	27.2%	<0.0001
Prostatic Hyperplasia	27.3%	25.1%	0.0151
Acquired Hypothyroidism	20.3%	25.2%	<0.0001
Select PD-Related Comorbidities			
Dementia[1]	3.8%	9.5%	<0.0001
Drug Induced Dyskinesia[1]	6.7%	3.3%	<0.0001
Hallucinations[1]	4.9%	4.1%	0.0529
LEDD (Mean, SD)	1,088 (642)	759 (432)	<0.0001
Levodopa-Containing Pills Per Day (Mean, SD)	8.7 (8.4)	6.3 (3.1)	<0.0001

1. Conditions are defined as ≥1 inpatient or ≥2 outpatient claims with the indicated diagnosis
APD: advanced Parkinson's disease; CCI: Charlson Comorbidity Index; DAT: device-aided therapy; LEDD: levodopa equivalent daily dose; SD: standard deviation

Disclosures

Author Disclosures
Alison Silverstein, Jill Schinkel, and Christie Teigland are employees of Inovalon, Inc. Connie Yan is an employee of AbbVie and may own stocks/shares in the company.

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References

[1] Marras, C., Beck, J. C., Bower, J. H., Roberts, E., Ritz, B., Ross, G. W., ... & Tanner, C. M. (2018). Prevalence of Parkinson's disease across North America. NPJ Parkinson's disease, 4(1), 1-7.
[2] Yang W, Hamilton JL, Kopil C, Beck JC, Tanner CM, Albin RL, Ray Dorsey E, Dahodwala N, Cintina I, Hogan P, Thompson T. Current and projected future economic burden of Parkinson's disease in the U.S. NPJ Parkinsons Dis. 2020 Jul 9;6:15. doi: 10.1038/s41531-020-0117-1. PMID: 32665974; PMCID: PMC7347582.
[3] Bastide, M. F., Meissner, W. G., Picconi, B., Fasano, S., Fernagut, P. O., Feyder, M., ... & Bézard, E. (2015). Pathophysiology of L-dopa-induced motor and non-motor complications in Parkinson's disease. Progress in neurobiology, 132, 96-168.
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/203952s000lbl.pdf
[5] Rodriguez-Oroz, M. C. (2010). Deep brain stimulation for advanced Parkinson's disease. The Lancet. Neurology, 9(6), 558-559.

Table 3. SDOH Characteristics

	APD Patients Who Received Any DAT	APD Patients Who Did Not Receive DAT	P-Value DAT vs. No DAT
Unique Number of Patients	2,447	110,167	
Household Income (USD)			
Mean ($)	72,220	71,048	0.0050
<$30,000	3.6%	4.3%	0.0221
$30,000 - $39,999	12.5%	12.9%	
$40,000 - $49,000	16.6%	18.6%	
$50,000 - $74,999	31.0%	30.6%	
≥$75,000	36.3%	33.6%	
Other SDOH Factors (Mean % of Neighborhood)			
Household Size	2.6%	2.6%	0.7248
Married	46.5%	45.9%	0.0197
Completed High School or Less	34.7%	35.9%	0.0001
Speaking English Not Well or Not at All	2.7%	3.0%	0.2941
Veterans	8.3%	8.1%	0.0010
Unemployed	3.2%	3.3%	0.0335
No Vehicle	6.3%	7.1%	0.0001

APD: advanced Parkinson's disease; DAT: device-aided therapy; SDOH: social determinants of health; USD: US dollars

Table 4. Healthcare Resource Utilization

	APD Patients Who Received Any DAT	APD Patients Who Did Not Receive DAT	P-Value DAT vs. No DAT
Unique Number of Patients	2,450	110,323	
All-Cause HRU (Patients with ≥1)			
Hospitalizations	22.1%	24.4%	0.0072
Length of Stay[1] (Mean, SD)	3.3 (4.9)	4.9 (16.9)	<0.0001
ER Visits	37.6%	36.9%	0.4821
Neurologist Visits	72.9%	66.6%	<0.0001
Neurosurgeon Visits	42.2%	4.5%	<0.0001
Gastroenterologist Visits	17.5%	9.9%	<0.0001
Geriatrician Visits	0.9%	1.1%	0.3480
Psychiatrist Visits	9.8%	5.8%	<0.0001
Post-Acute Care	20.5%	28.7%	<0.0001
Number of Days (Mean, SD)	4.1 (14.0)	8.8 (30.0)	<0.0001
Durable Medical Equipment			
Wheelchair	2.7%	4.5%	<0.0001
Walker	4.9%	4.8%	0.8112
Specialty Bed	1.2%	2.7%	<0.0001

1. Length of stay is calculated among patients with ≥1 stay
APD: advanced Parkinson's disease; DAT: device-aided therapy; ER: emergency room; HRU: healthcare resource utilization; SD: standard deviation

Limitations

- The analysis was conducted in Medicare population consisting of primarily patients over the age of 65, which limits generalizability to other populations.
- In the lack of clear definition of APD, the use of proxies to define patients with APD may either under or overestimate this population.
- The different index dates for each cohort may capture patients at different severity of PD.
- Short baseline and follow-up periods due to the fragmentation of care may impact the evaluation of PD and APD populations, and DAT use.

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