

# The Silver Book®: Parkinson's Disease



## The Silver Book®: Parkinson's Disease

Parkinson's disease is a progressive neurological disorder that leads to debilitating symptoms, comorbidities, expensive medical care, and caregiving needs. Existing therapies help manage symptoms and exciting research advances hold promise for even better management and potential cures.

### Age – A Major Risk Factor

**70½**  
YEARS OLD

= AVERAGE AGE of  
**Parkinson's disease**  
diagnosis in the U.S.  
(Van Den Eeden et al. 2003)

2.17%

1.33%

.29%

.01%

≤49

50 - 64

65 - 74

≥75

AGE

Parkinson's Disease Prevalence Increases with Age (Hamilton & Yang et al. 2019)

### Prevalence & Incidence



~1 **MILLION**  
**AMERICANS**

have **PARKINSON'S DISEASE**

(Marras et al 2018 AND Hamilton & Yang et al. 2019)

**MEN ARE**  
**1.37x**  
**MORE LIKELY**



to have Parkinson's  
disease than women

(Hamilton & Yang et al. 2019)

In the U.S., **Parkinson's disease** is  
the **2ND** **MOST COMMON**  
**NEURODEGENERATIVE DISORDER**

(NINDS 2018)



**EVERY**  
**9 MINUTES**,

someone in the U.S.  
is **DIAGNOSED** with  
**Parkinson's disease** —

~**60,000** **NEW** cases each year

(Parkinson's Foundation)

**The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation** is an almanac of thousands of facts, statistics, graphs, and data from hundreds of agencies, organizations, and experts. These statistics spotlight the mounting burden of chronic diseases that disproportionately impact older Americans, and the promise of innovation in mitigating that burden.

Launched in 2006, *The Silver Book®* has become a trusted resource for health policy practitioners and thought leaders and has featured volumes and factsheets on valve disease, osteoporosis, thrombosis & atrial fibrillation, heart disease, persistent pain, cancer, healthcare-associated infections, infectious diseases & prevention through vaccination, vision loss & diabetic retinopathy, diabetes, and neurological diseases. All data is available online at [www.silverbook.org](http://www.silverbook.org), where users can access more than 3,000 facts, statistics, graphs, and data from more than 800 references. All data is cited and when possible, linked to the original source online.



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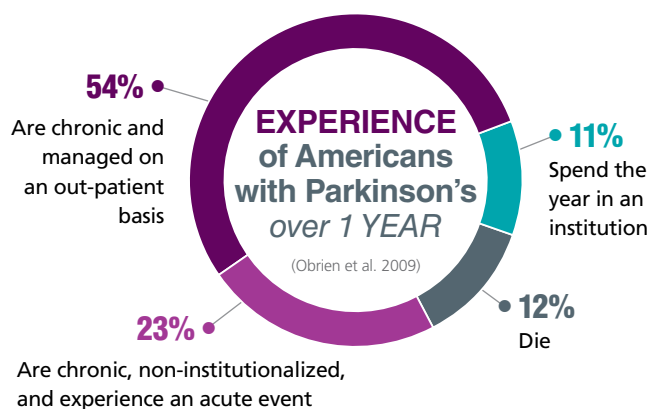
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# Human Burden

 **>23 THOUSAND**  
**PREMATURE DEATHS**  
**associated with Parkinson's disease**

in 2017 (Hamilton & Yang et al. 2019)

**MORTALITY**  
**>3x GREATER**  
for PEOPLE WITH PARKINSON'S than  
for those without the disease (Hamilton & Yang et al. 2019)



**DEMENTIA** is **NEARLY INEVITABLE** for people with Parkinson's disease — affecting **MORE THAN 80%** of people followed for **>20 YEARS** after disease onset

(Biundo et al. 2016)

**Depression may affect:**

UP TO **50%** of people with Parkinson's disease — YET **40% DO NOT receive treatment**

(Tandberg et al 1996 AND Ravina et al. 2007)

**>1/2** of people with Parkinson's **eventually develop symptoms of PARKINSON'S DISEASE PSYCHOSIS**

(Forsaa et al. 2010)

**~60%** of people with Parkinson's disease report **at least one fall** and recurrent fallers report **4.7 to 67.6 falls per year** (Allen et al. 2013)



The risk of **suffering a fracture** is **2x HIGHER** in people with Parkinson's disease, and the risk of a **hip fracture** is **>3x HIGHER**

(Melton et al. 2006)

**Percentage of People with Parkinson's who Experience Various Symptoms** (Hamilton & Yang et al. 2019)

Slowed movement	91%
Tremors	82%
Poor balance and coordination	89%
Trouble speaking	70%
Trouble writing	86%
Urinary issues	78%
GI issues	78%
Sleep issues	86%
Fatigue and loss of energy	93%
Difficulty concentrating	78%
Difficulty with memorizing or recalling information	79%
Difficulty understanding complex tasks	63%
Difficulty swallowing	60%
Vision problems	58%
Pain	66%

**In 2010, Parkinson's disease was attributed to:**

<b>26,000</b>	hospice days
<b>24,000</b>	home health days
<b>31,000</b>	emergency room visits
<b>1.26 million</b>	physician office visits
<b>1.9 million</b>	hospital inpatient days

(Kowal et al. 2013)

Nearly **1 in 4** Medicare beneficiaries with Parkinson's disease **LIVED IN A LONG-TERM CARE FACILITY** in 2002 (Safarpour 2015)

# Economic Burden

TOTAL ANNUAL COST OF PARKINSON'S DISEASE IN THE U.S.

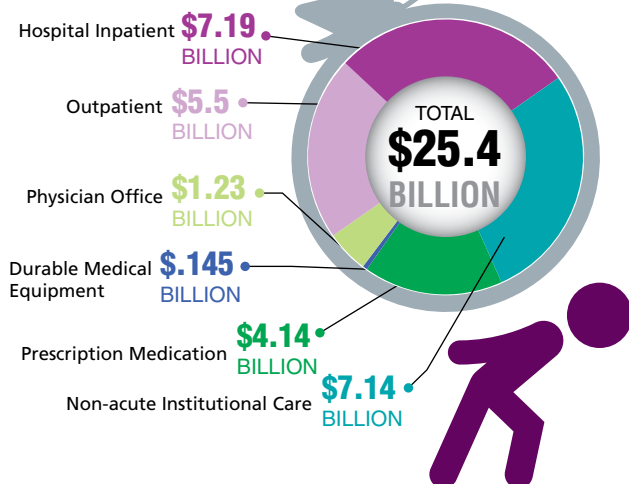
**= \$51.9 BILLION**

As part of its initiative to better understand the economic burden of Parkinson's disease, the Michael J. Fox Foundation for Parkinson's Research commissioned The Lewin Group to estimate the economic impact of Parkinson's disease in the U.S., based on 2017 data and completion of a primary survey deployed in the wider Parkinson's disease and caregiver community. The study provides the most comprehensive assessment of the economic burden to date, nearly doubling previous estimates, and for the first time, includes the various ways Parkinson's affects a person's finances and their ability to participate in the labor market. The Economic Burden of Parkinson's Disease, was published with support from Parkinson's Foundation, American Parkinson Disease Association, and The Parkinson Alliance, along with ACADIA, Adamas, AbbVie, Acorda, and Biogen.

(Hamilton & Yang et al. 2019)

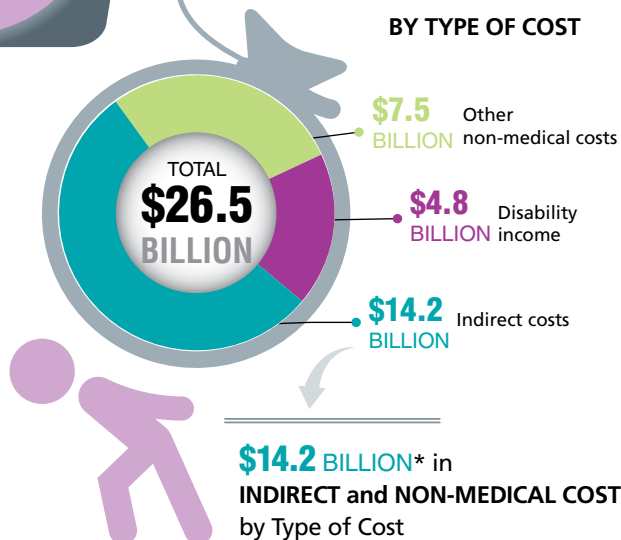
**\$25.4 billion**  
in DIRECT MEDICAL COSTS

## BY TYPE OF SERVICE



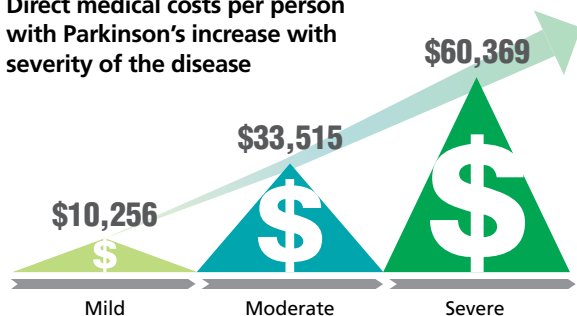
**\$26.5 billion**  
in INDIRECT MEDICAL COSTS

## BY TYPE OF COST

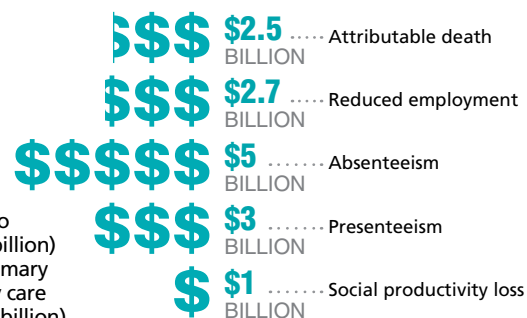


AVERAGE ANNUAL DIRECT MEDICAL COST per person with Parkinson's is **= \$24,439** MORE THAN if they DIDN'T HAVE the disease

Direct medical costs per person with Parkinson's increase with severity of the disease



\*Includes cost to patient (\$7.7 billion) and cost to primary and secondary care partners (\$6.5 billion)



AVERAGE ANNUAL INDIRECT & NON-MEDICAL COSTS per person with Parkinson's disease =

**\$19,242** : **\$25,558** when combined with caregiver burden

The FEDERAL GOVERNMENT spends **NEARLY \$25 BILLION EACH YEAR** caring for people with Parkinson's —

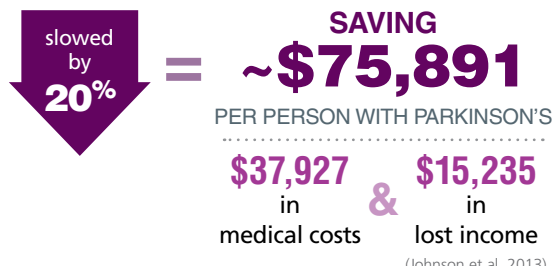
**= ~\$2 billion on social security + \$23 billion on Medicare costs**

**~90%** of the Parkinson's disease population are on Medicare



# Value of Innovation

IF PARKINSON'S DISEASE PROGRESSION WAS:



In 2018, **46 medicines** were in development for Parkinson's disease  
 (America's Biopharmaceutical Companies 2018)

**Exciting momentum in the understanding of Parkinson's disease holds tremendous promise for breakthroughs in treatment and improved care.** Treatments like gene therapy and stem cell therapy hold the potential to slow and even stop the disease; next generation therapies aim to treat many of the symptoms of the disease, including non-motor symptoms, and may even improve quality of life (QoL); and the quest for biomarkers is being prioritized by researchers. These and other promising advances are bringing hope to people living with Parkinson's.

A **GENE THERAPY** that makes an **enzyme allowing better communication between cells in the nervous system**, was found in early stage clinical trials to **REDUCE THE AMOUNT OF LEVODOPA** the subject needed to take — **up to 42% less** in the highest dose group (Christine et al. 2019)



A **GENE THERAPY** that **encodes for the three critical enzymes required for dopamine production**, was found in early stage clinical trials to produce a **42% improvement** in **UPDRS OFF scores and improvements in activities of daily living**, 3 months after treatment (Lopes 2019)

**Deep brain stimulation** can **REDUCE MOTOR DISABILITY** and in one study, **added 1.69 quality-adjusted life years (QALY)** more than best medical therapy, **= an incremental cost-effectiveness ratio of: \$23,404 per QALY** (Pietzsch et al. 2016)



Early findings from a **STEM CELL THERAPY TREATMENT** study found **improved motor function** in Parkinson's subjects with mild to moderate disease (Schiess et al. 2019)

**Spinal cord stimulation** **SIGNIFICANTLY IMPROVED gait disturbance & freezing** — improving measures

MEAN STEP LENGTH	STRIDE VELOCITY	SIT-TO-STAND
<b>38.8%</b>	<b>42.3%</b>	<b>50.3%</b>

Also significantly **reduced freezing-of-gait (FoG) episodes** — from 16 pre-surgical FoG episodes to 0 at 6 months post-surgery

(Samotus et al. 2018)

## Power of Collaboration

Forward-thinking collaborations that bring together stakeholders across sectors offer tremendous promise for breakthroughs. The Accelerating Medicines PD Knowledge Portal that houses data from more than 3,000 people with Parkinson's and is working to identify and validate the most promising therapeutic targets; and the Biomarkers Across Neurodegenerative Disease Partnership that aims to increase understanding of the similarities and differences of neurodegenerative diseases; are both important examples of the power of collaboration.

# Paving the Way for Innovative Treatments

## Engaging and Incorporating the Patient and Care Partner Perspective

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The participation and perspective of people with Parkinson's disease are critical to developing effective therapies, yet fewer than 10% participate in research. Participation must be encouraged and facilitated through projects like:

- **Clinical Trial Companion and the Trial Participant Pack** – tools that help educate on what it means to participate in a clinical trial and how to get involved
- **Fox Insight** – on-line clinical study where patients share perspectives to help fuel treatment breakthroughs
- **Genetics Initiative** – national study offering free genetic testing and counselling for Parkinson's-related genes
- **Parkinson's Outcome Project** – largest ever clinical study of Parkinson's disease
- **Parkinson's Progression Markers Initiative** – observational study of cohorts to identify biomarkers of Parkinson's disease progression
- **PD Information Questionnaire (PDIQ)** – brings patients together to determine what clinical trial outcomes are most important to them

## Ensuring Patient Access to Treatments

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Parkinson's disease patients have unique challenges — often dealing with the complexity of the disease; symptoms that can have substantial social implications; comorbidities like depression, anxiety, and other chronic disease; and elaborate treatment regimens that can include physical, occupational, and cognitive therapy. Treatment delays and/or interruptions in care can cause symptoms to return and new side effects to develop. Given the complexity of the disease, once the most appropriate treatment is identified, access to treatment must be broad and uninterrupted. Utilization management tools should not be used to steer patients to lower cost alternatives if not clinically appropriate; and if used, clear and timely processes must be available for the physician to gain a medical exception when clinically appropriate.

## Evolving Payment Models for Gene Therapy

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Breakthroughs in gene therapy have enormous potential to transform approaches to Parkinson's disease treatments. Commercial health plans, manufacturers, and the Centers for Medicare and Medicaid Services will need the regulatory ability to adopt creative payment models to enable the community to broadly benefit from the promise of gene therapy while continuing to enable companies to fund innovation. Possible solutions could include:

- Outcomes-based contracts that share risk
- Shared savings across the system
- Installment payment contracts that delay the costs of treatment
- Commonly funded risk pools for insurers

## Safeguarding the FDA's Workforce and Maximizing Use of Regulatory Tools

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As the Food and Drug Administration (FDA) undertakes a major reorganization, it is imperative that the agency hire and retain staff with the neurology and psychiatry expertise necessary to review a new generation of Parkinson's disease treatments; and that it maximizes the use of innovative regulatory tools. Priorities set through recent legislation must continue to be supported including:

- Creation of pilot programs to modernize and streamline hiring
- Increased use of designations such as Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, and Regenerative Medicine Advanced Therapy
- Prioritization of efforts to better understand disease domains, patient populations, and improved ways of measuring treatment effect

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