



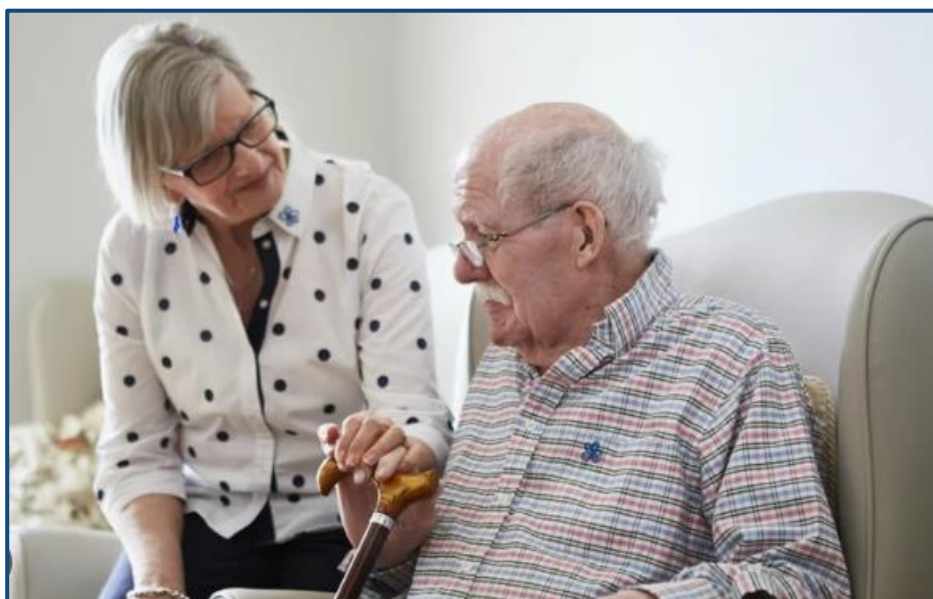
## Improving Care of Dementia: The Path Forward

September 2023

# AVONDALE PARTNERS



## Introduction



- Alzheimer's is among the costliest diseases in the U.S. with an annual direct cost of \$345 billion, second only to diabetes<sup>1</sup>
- Though cognitive impairment ("CI"), and its severest form, Alzheimer's, is recognized as the most debilitating chronic disease, until recently little progress has been made in improving care for individuals with CI

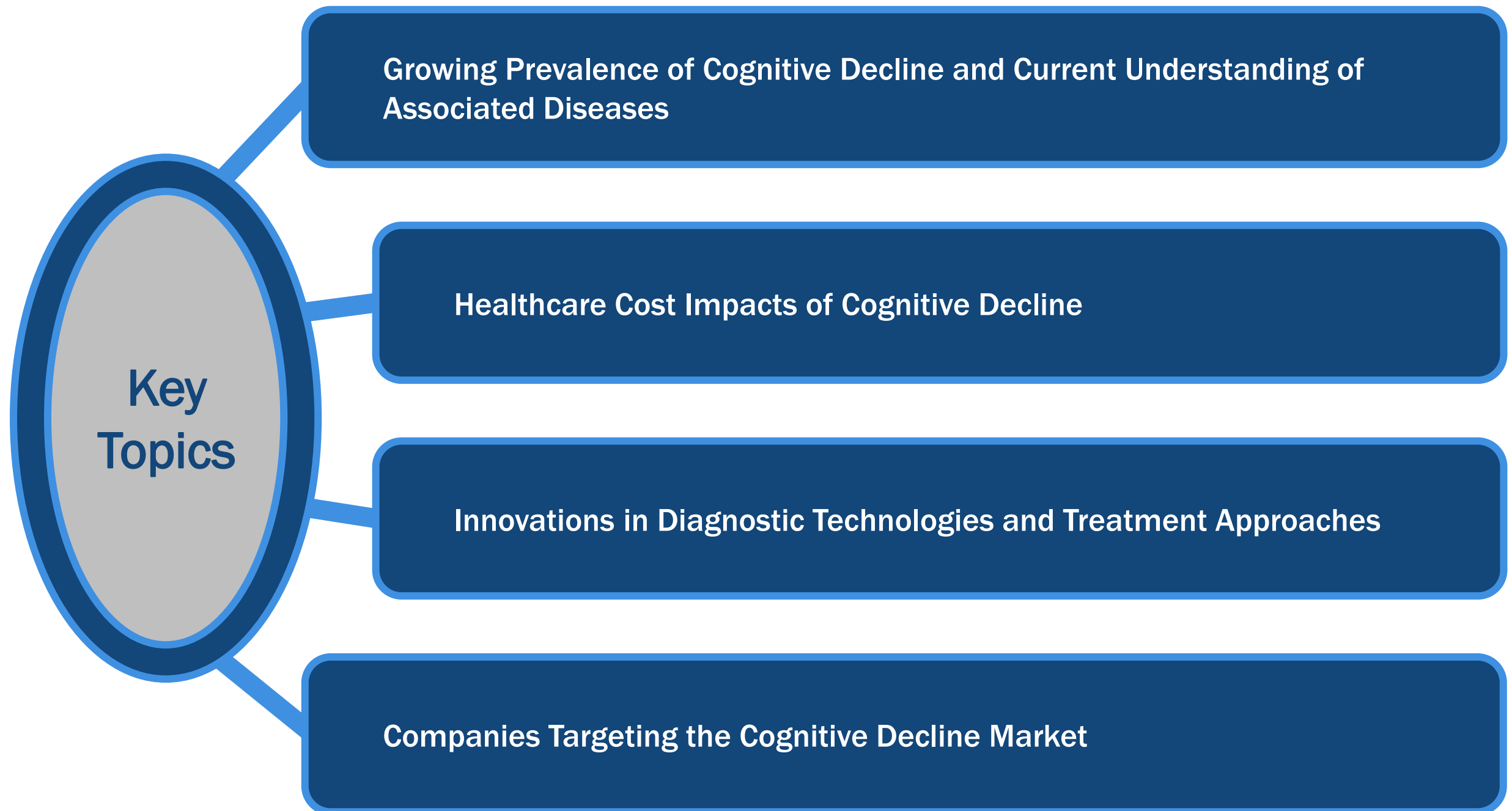
- With improved understanding of the over 50 risk factors of CI, there has recently been important technology-driven breakthroughs in early diagnosis, care and pharmaceutical treatment of the disease
- Though there is no cure, these recent developments, and many more under research, promise to better diagnose and delay the onset of the most serious symptoms and provide better care for these individuals



**This sector insight reviews the breadth of this chronic disease, its financial impact for both the healthcare system and caregivers, and discusses some of the breakthrough technologies and care providers that are beginning to change the face of this disease**

## Improving Care of Dementia: The Path Forward

Due to recent research discoveries and the approval of several new Alzheimer's drugs, the standard treatment of patients with Cognitive Decline is rapidly evolving



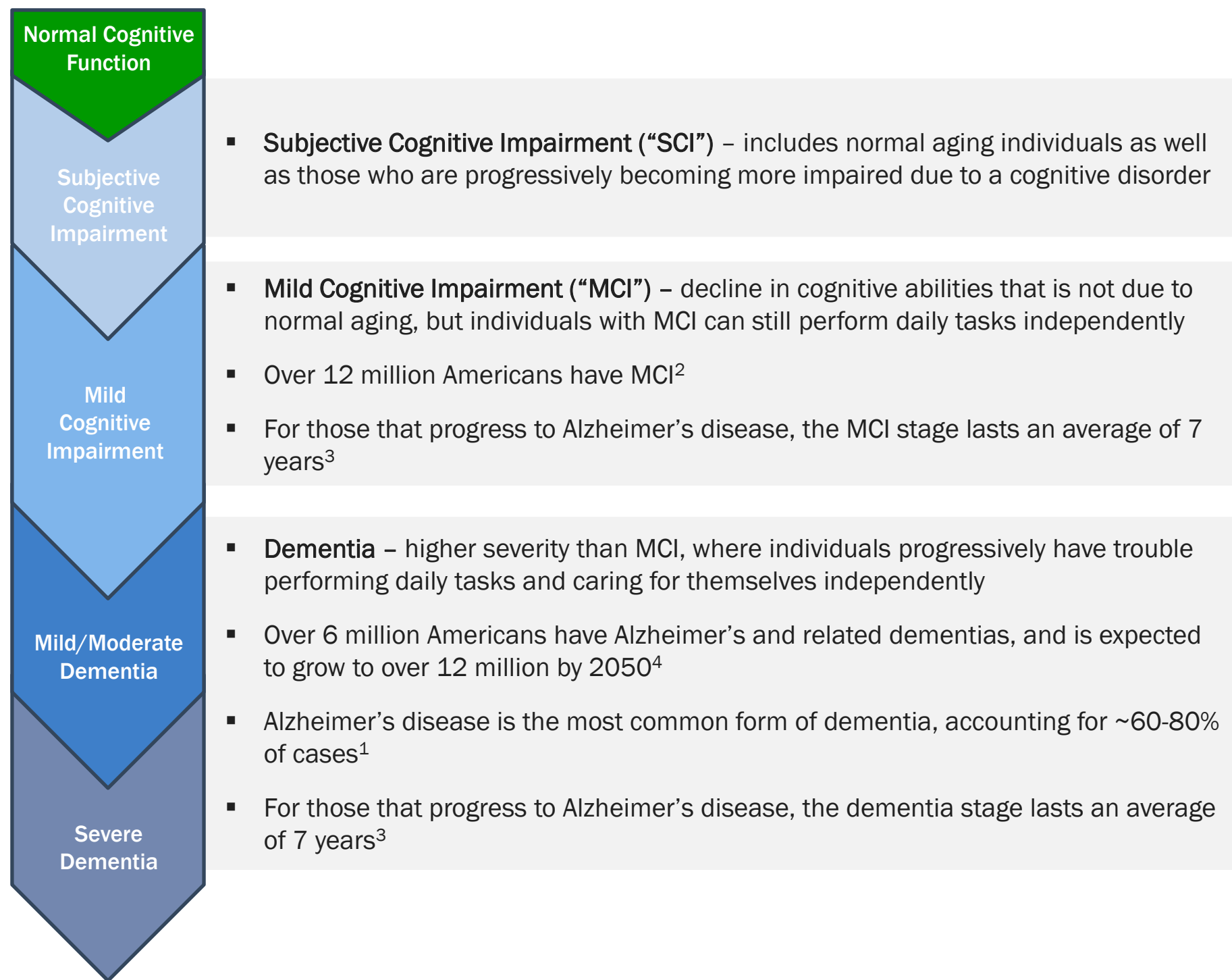
# What is Cognitive Decline?

*Cognitive Decline develops over a period of 20–30 years, increasing in severity over time if left untreated<sup>1</sup>...*

*~2 out of 3 Americans will experience Cognitive Decline in their lifetime<sup>2</sup> ...*

*~1 in 3 Americans age 65 or older have Mild Cognitive Impairment or Alzheimer’s/ Dementia – or ~18 million Americans*

Cognitive Decline (“CD”), also known as Cognitive Impairment, affects a person’s memory, language, thinking, or judgement to a greater degree than with normal aging and ranges in severity



Source: (1) Nature Aging - Towards a future where AD pathology is stopped before the onset of dementia (2) SSM Population Health - Cognitive Impairment in the U.S. (3) hoag.org - Cognitive Severity Stages (Normal Aging – Dementia) (4) Alzheimer’s Association

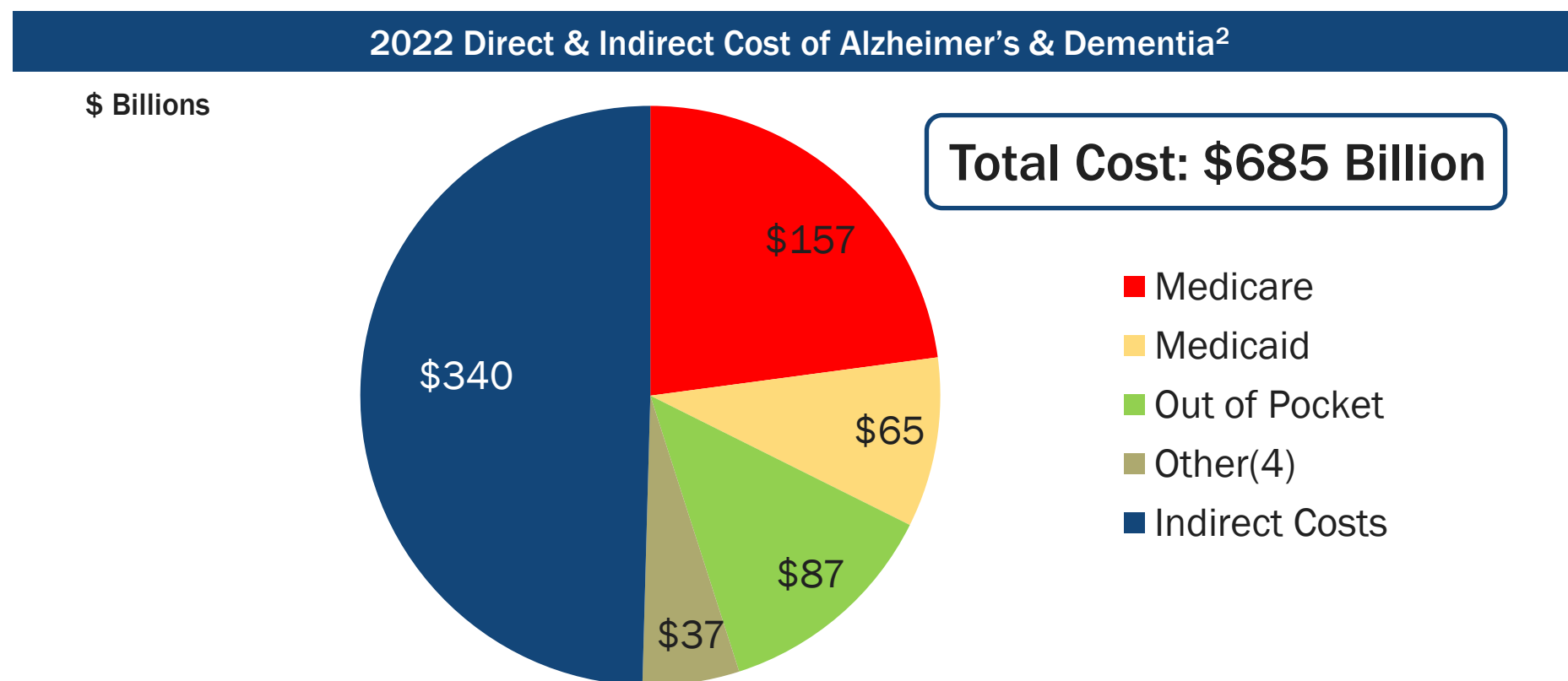
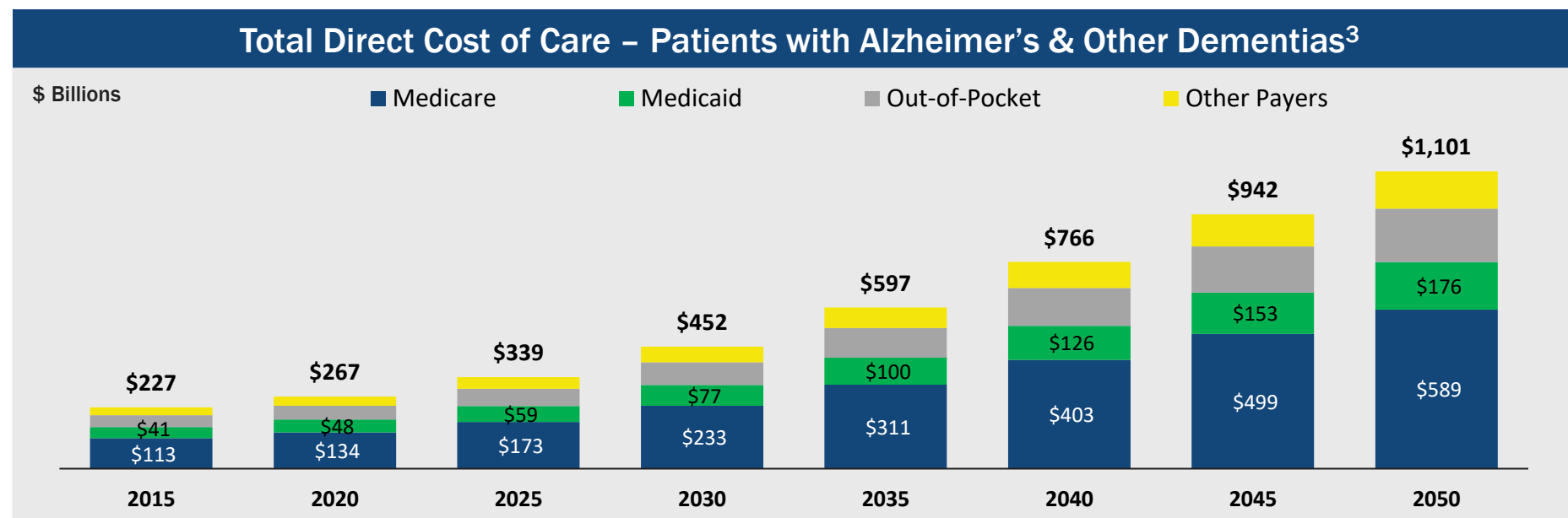
# Financial Impact of Cognitive Decline

Direct cost of care of **\$345 billion** attributed to dementia is larger than any other disease, and will grow significantly with the aging population...

2023 estimated Medicare and Medicaid costs attributable to Alzheimer's and dementia represent **~12%** of all Medicare and Medicaid projected expenditures<sup>1</sup>...

**\$685 billion** – Direct and indirect cost of care provided to Americans with Alzheimer's in 2022<sup>2</sup>

The total direct cost of care for patients suffering from Alzheimer's or other dementias is expected to reach **\$345 billion** in 2023, costing Medicare and Medicaid **~\$222 billion** for these patients alone<sup>2</sup>



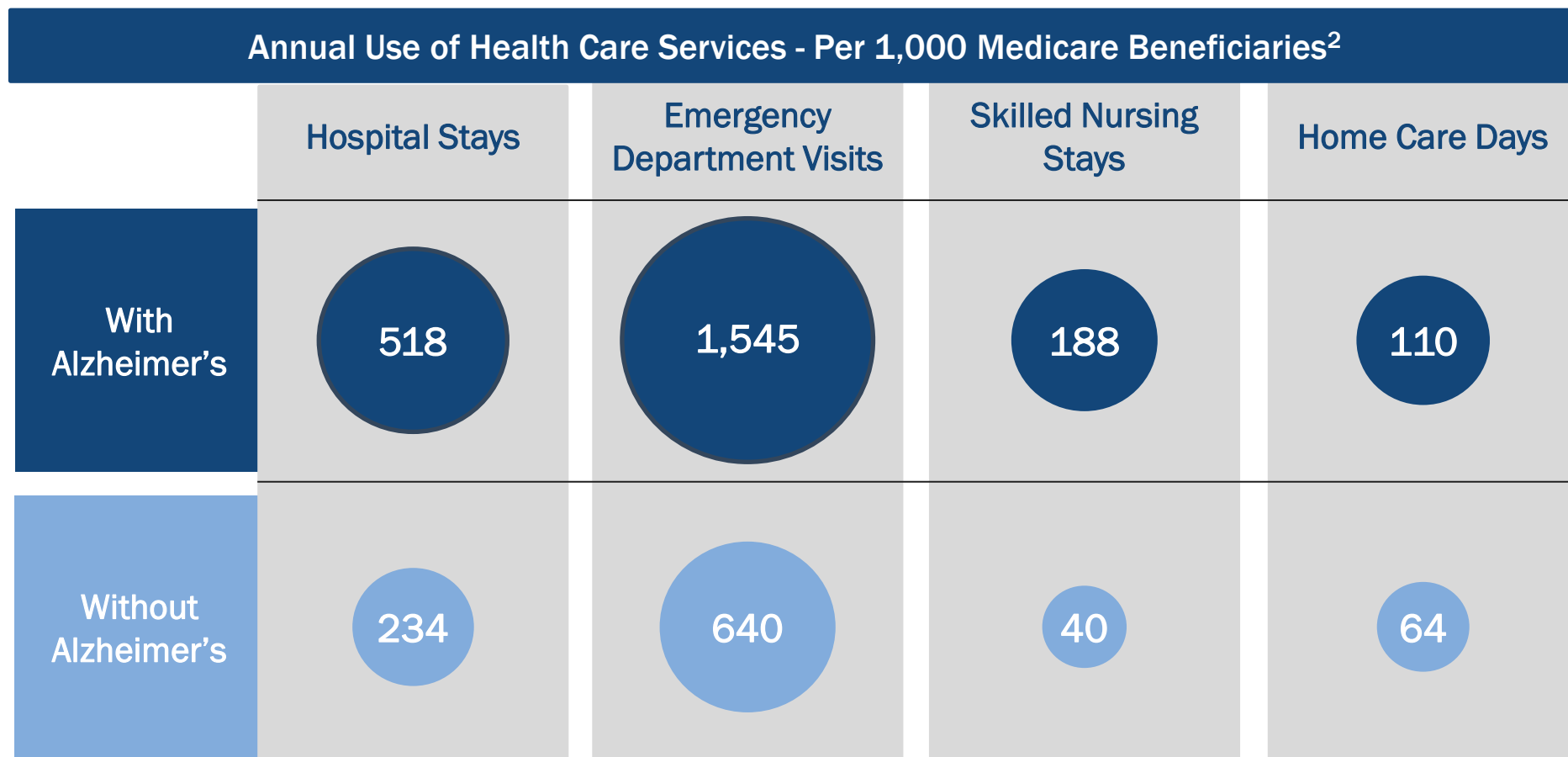
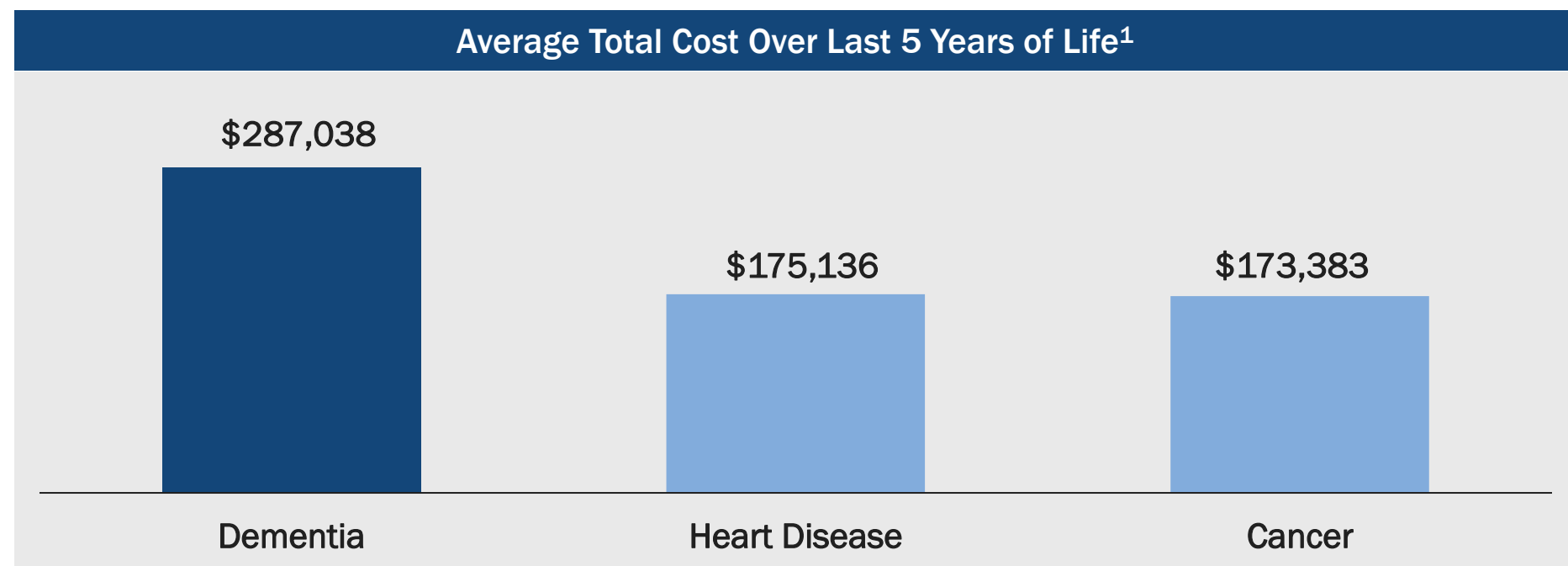
Source: (1) Office of the Actuary in the Centers for Medicare & Medicaid Services – NHE Projections Forecast Summary (2) Alzheimer's Association – 2023 Alzheimer's Disease Facts and Figures, (3) "Changing the Trajectory of Alzheimer's Disease" Alzheimer's Association, 2015. (4) Other includes private insurance, HMO, other managed care and uncompensated care

## Financial Impact of Cognitive Decline

*Dementia's total cost over the last 5 years of life far exceeds the top 2 leading causes of death...*

*People with Alzheimer's and dementia have substantially higher use of healthcare services...*

*Many of the expenses associated with Alzheimer's and dementia are uninsured, thus placing a large financial burden on families<sup>1</sup>*



Source: (1) Annals of Internal Medicine – The Burden of Health Care Costs For Patients With Dementia in the Last 5 Years of Life (2) Alzheimer's Association – 2023 Alzheimer's Disease Facts and Figures,



## Progression of Cognitive Decline Treatment

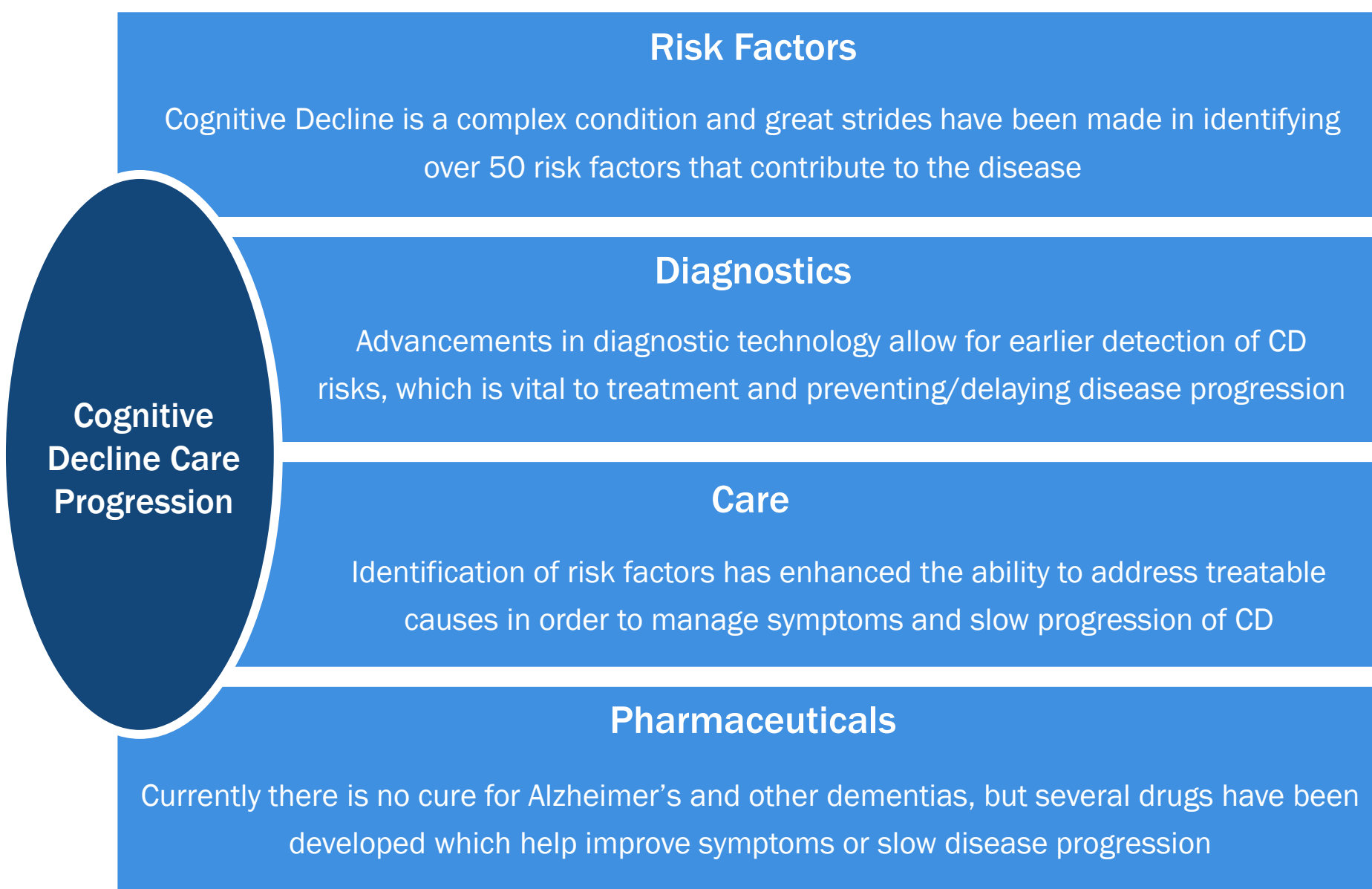
*Historically, Alzheimer’s and dementia patients were treated with medications to manage symptoms and told to “get their affairs in order”...*

*Today, there is a much better understanding of the potential causes of cognitive decline...*

*Increased awareness and funding across the CD care continuum has prompted innovations in the diagnosis and treatment of patients with CD*

Physicians previously had little understanding of CD, and diagnosis only occurred once individuals reached the severe phases of Alzheimer’s

- Physicians who had identified patients with CD only sought to ease symptoms, not address treatable causes



## Known Risk Factors Of Cognitive Decline

*There are 50+ known risk factors of CD that, if addressed can slow or eliminate certain symptoms of Alzheimer's and dementia...*

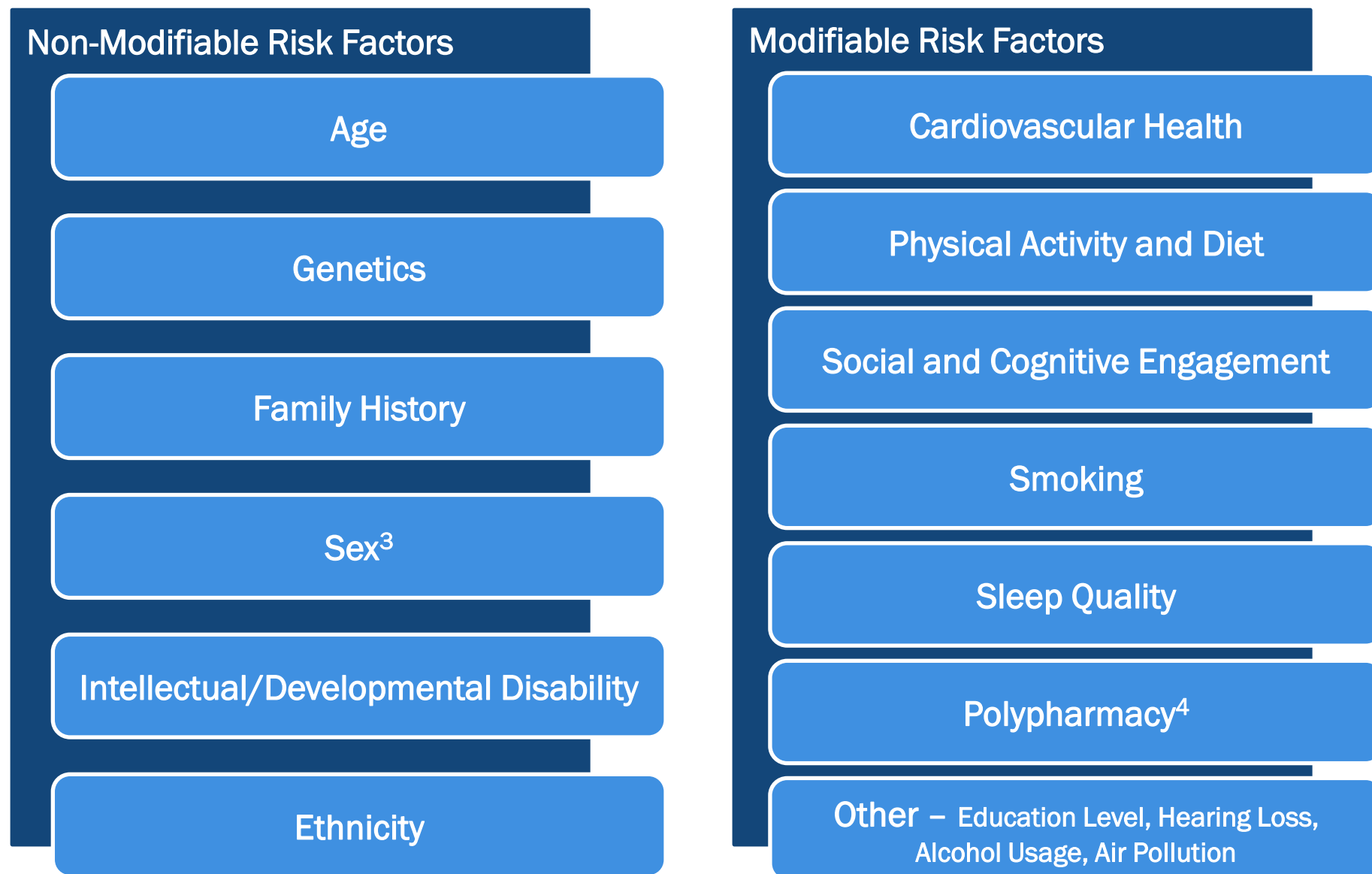
*12 modifiable risk factors account for ~40% of worldwide dementias<sup>2</sup>...*

*The ability to treat cognitive decline is a recent discovery and an important step in fighting what was previously known as an untreatable disease*

**Non-modifiable risk factors account for some of the greatest risks in developing Alzheimer's and dementia**

- Age is the greatest risk factor, with ~33% of people age 85+ having Alzheimer's, followed by genetics and family history<sup>1</sup>

**Despite the impact of non-modifiable risk factors, a growing body of evidence indicates that modifiable risk factors play a significant role in developing Alzheimer's disease**



Source: (1) Alzheimer's Association – 2023 Alzheimer's Disease Facts and Figures, (2) Lancet Commission – Dementia Prevention, Intervention, and Care (3) Females are more likely to be diagnosed with cognitive decline, as compared with males (4) Elderly patients taking at least 5 medications are at increased risk of cognitive decline



# Diagnosing Cognitive Decline

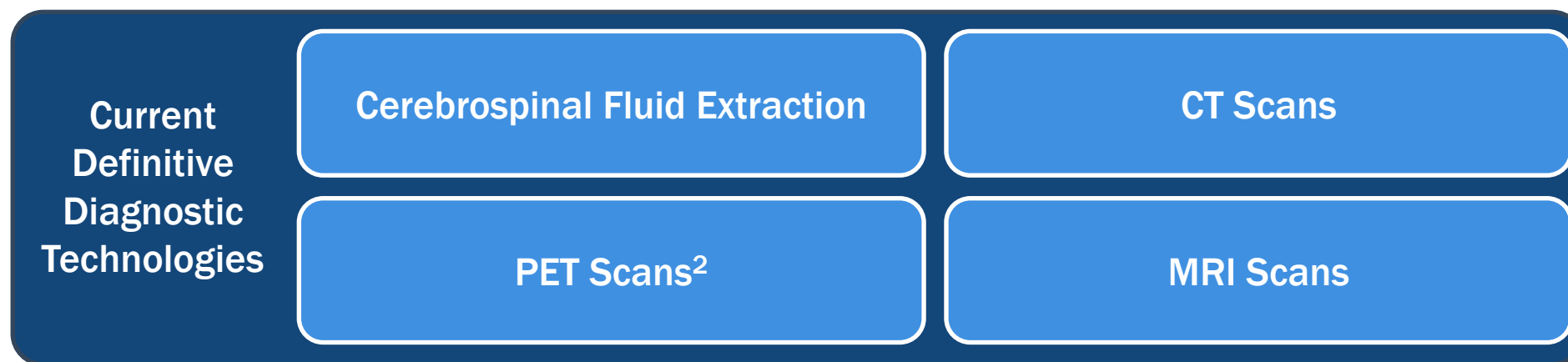
*Stigmas surrounding dementia, along with misconceptions that it is a natural part of aging, have caused worldwide underdiagnosis...*

*Early diagnosis is key to preventing or delaying disease progression...*

*Innovations in definitive diagnostic technologies will enable more patients to better address their treatable causes at an earlier disease state*

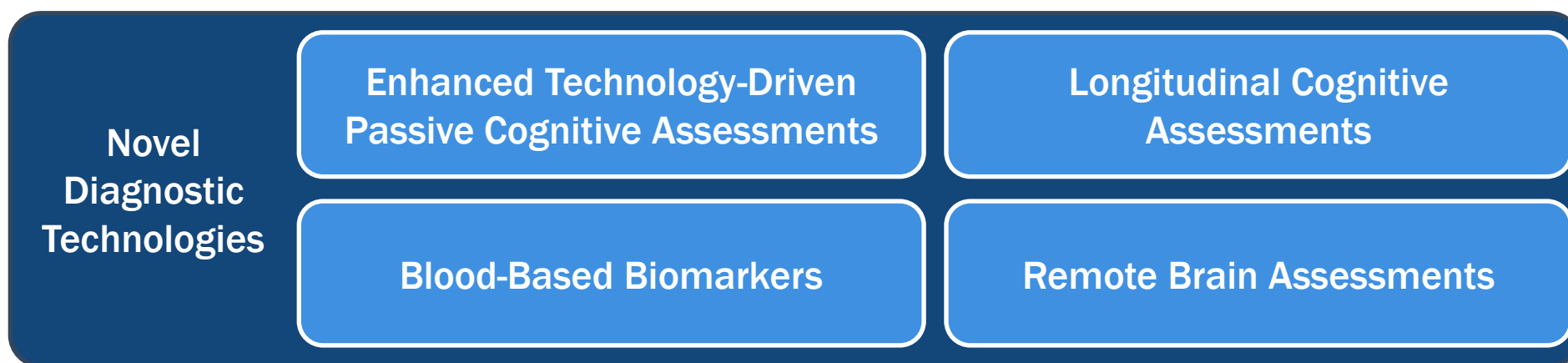
Screening for CD is required by Medicare as part of annual wellness visits, but current definitive diagnostics tend to be very invasive and cost prohibitive<sup>1</sup>

- Prior to a definitive diagnostic test, patients must take a simple pen-and-paper cognitive assessment to determine whether they may have cognitive decline



Routine definitive testing for CD will require novel diagnostic approaches offering scalable, repeatable, more cost-effective solutions







- Novel diagnostics have yet to receive FDA approval or CMS reimbursement



Source: (1) Translational Psychiatry – Developments in Scalable Strategies for Detecting Early Markers of Cognitive Decline (2) Currently, PET scans are not reimbursable by CMS unless done through a CMS-approved clinical trial

## Cognitive Decline Diagnostic & Assessment Companies

The global cognitive assessment market was valued at \$3.9 billion in 2022, and is expected to grow to \$29.7 billion by 2030, growing at a CAGR of 29.2%<sup>1</sup>

Company	Description	Total Amount Raised	Selected Investors
	Developer of brain health assessment and neurocognitive test platform for detecting Alzheimer’s and dementia	\$21.3mm	Eisai Innovation; Hikma Ventures; M Ventures; Alzheimer’s Drug Discovery Foundation
	Platform including comprehensive cognitive and behavioral health assessment, clinical decision support, and cognitive care planning	\$27.1mm	Gershon Capital; UPMC Enterprises; Next Coast Ventures; Nueterra Capital; GOOSE Capital
	Diagnostics company offering high-resolution mass spectrometry-based biomarker services focused on Alzheimer’s	\$35.0mm	Alzheimer’s Drug Discovery Foundation; NIH; GHR Foundation
	Digital platform including assessments, clinical decision support, and personalized action planning for those with cognitive decline	\$64.8mm	Morningside Group
	Platform offers cognitive health programs to assess, preserve and strengthen memory health to reduce risk of future cognitive decline	\$57.6mm	Johnson & Johnson; Founders Fund; Khosla Ventures; AME Cloud Ventures; NIH
	World’s leading provider of diagnostic testing and information services	Public	Public

Source: (1) Fortune Business Insights – Cognitive Assessment and Training in Healthcare Market  
Company Websites, Pitchbook

# Addressing Cognitive Decline Through Care Planning

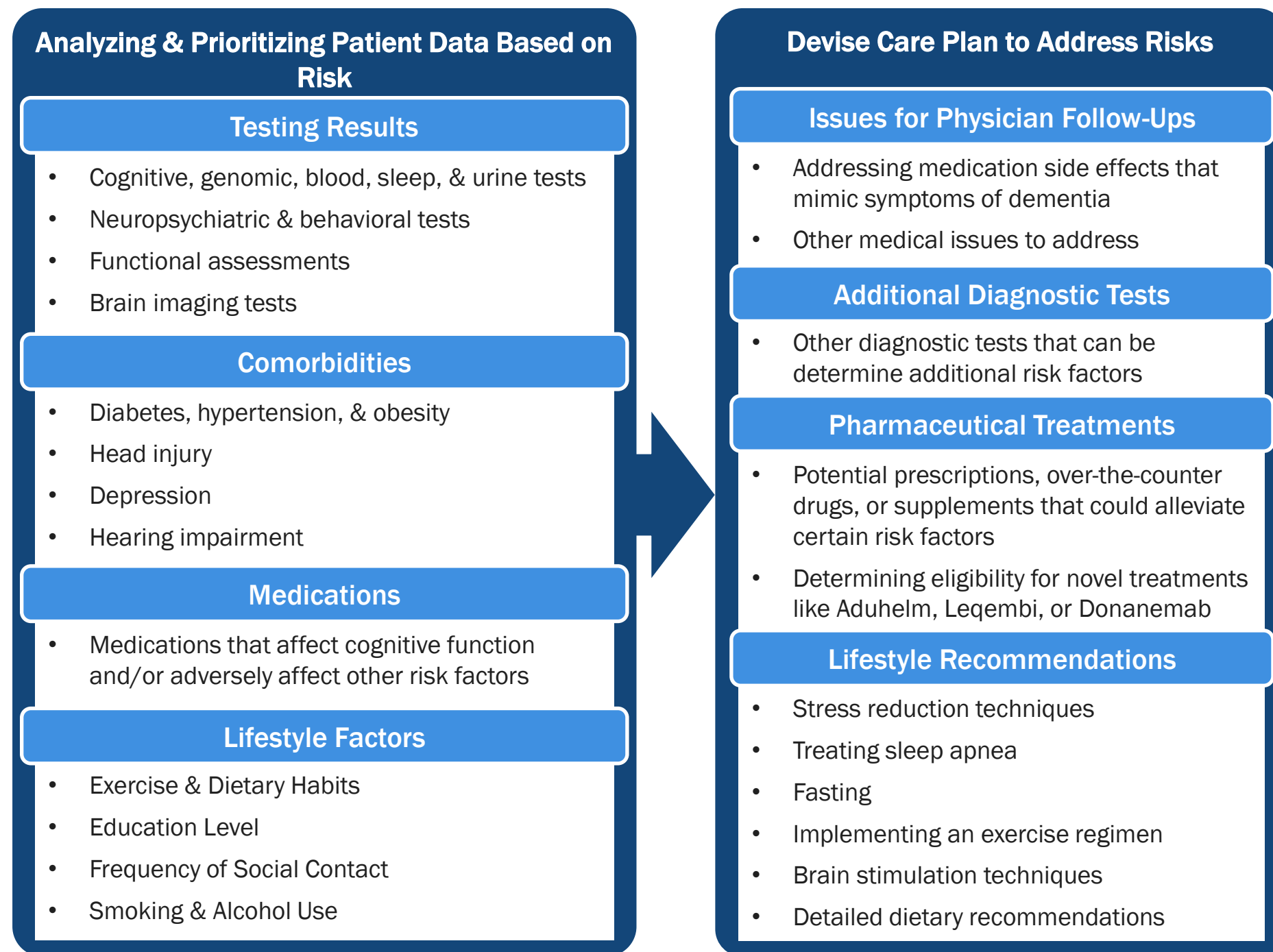
*Reimbursable care planning is emerging as a major treatment pathway that can address the modifiable risk factors of cognitive decline...*

*Specific changes can more effectively slow or alter the progression of cognitive decline...*

*Detailed care plans proactively address cognitive decline through effective combinations of treatments, lifestyle changes, supplements and medications*

**CMS recognizes the growing problems associated with cognitive decline, and in 2018 created CPT code 99483 to reimburse physicians for developing written care plans for patients at risk of CD**

- Leveraging diverse patient data to create personalized cognitive care plans provides a proactive treatment solution to patients



## Cognitive Decline Care Planning Companies

Despite nearly 18 million Americans suffering from MCI and Alzheimer's, only ~83,000 care plans were submitted for reimbursement by CMS in 2021<sup>1</sup>

- This massive unmet need can be attributed to several factors:
  - Complex and time-consuming requirements needed to complete care plans
  - Physicians' lack of awareness that these care plans are reimbursable
  - Lack of proper discussions on cognitive decline between physicians and patients – according to the Alzheimer's Association only 3% of primary care physicians proactively discuss cognitive decline with patients during routine health visits



### Physicians, PAs, & NPs

Clinicians can provide and bill for care planning services

- According to a 2016 JAMA report, it is estimated that clinicians needed to create 35 million care plans annually for an estimated 18 million patients
- Today, due to complexity of CMS requirements there has been very limited adoption of cognitive care plans



uMETHOD has the first AI-powered platform to produce detailed cognitive care plans

- Analyzes patient's lab tests, health history, lifestyle habits, medications, and more
- Identifies treatable causes of cognitive decline that are active in the patient
- Provides patient-specific care plan that recommends to clinicians and patients effective combinations of treatments, lifestyle changes, supplements and medications



### BrainCheck

BrainCheck focuses on cognitive assessments, but has clinical decision-making and cognitive care planning tools

- Cognitive assessment tests memory, attention and executive function
- Clinical decision-making scores patients' cognitive health, tracks performance, likelihood of impairment and more
- Care planning tool helps providers build, document and deliver comprehensive care plans



## Pharmaceutical Treatments for Cognitive Decline

As of 2023, the FDA has approved 7 drugs for the treatment of Alzheimer's<sup>1</sup>...

Aduhelm and Leqembi represent the first new Alzheimer's drugs to gain FDA approval in nearly 20 years<sup>2</sup>...

Successful drug approvals point to a better understanding of Alzheimer's-related biology, laying the foundation for more productive drug development programs

Five therapies aim to improve symptoms, but do not affect the underlying brain changes that cause symptoms, nor do they alter the course of the disease

- Can be prescribed as monotherapies or combination therapies<sup>1</sup>



The FDA has approved two drugs which alter the course of the disease, while one other drug is seeking approval by the end of 2023 – all are immunotherapies that target beta-amyloid plaques

- While trials have exhibited signs of slowing the pace of CD progression, these drugs have been linked to serious side effects, such as brain swelling & brain bleed



- FDA Accelerated Approval in 2021
- Produced by Eisai and Biogen
- Annual list price - \$28,000<sup>3</sup>
- Covered by Medicare only for those in clinical trials
- Shown to reduce beta-amyloid plaques



- Approved by the FDA in July 2023
- Produced by Eisai and Biogen
- Annual list price - \$26,500<sup>4</sup>
- Covered by Medicare
- Shown to slow disease progression by 27% over an 18-month period

### Donanemab

- Seeking FDA approval by end of 2023
- Produced by Eli Lilly
- Results have shown that treating patients who are in the earliest stages of Alzheimer's can slow disease progression by 40-60%<sup>5</sup>

# Pharma Companies Targeting Alzheimer's

As of January 2023, there were **187 trials** assessing **141 unique treatments** for Alzheimer's<sup>1</sup>...

While amyloid-targeting therapies remain a prominent focus, the Alzheimer's drug development pipeline is diversifying across several targets and treatment modalities...

Given the complexity of Alzheimer's, it is likely that future treatments will involve a cocktail of expensive therapeutics

Pharma companies have increased their focus on developing medications targeted at preventing, delaying, or improving symptoms of Alzheimer's disease through a variety of pathological processes






## Alzheimer's Drug Pipeline – Approved & Clinical Trials Phase II/III

<p><b>Anti-Amyloid</b> (Reduces toxic amyloid plaques)</p>	<p><b>Anti-Tau</b> (Reduces toxic tau proteins)</p>
<p><b>Anti-Microbial</b> (Inhibits proteins released by periodontal bacteria)</p>	<p><b>Sigma-1 Agonists</b> (Activates receptors involved in mood and cognition)</p>
<p><b>Modulating Inflammation</b> (Changes immune system functions)</p>	<p><b>Repurposed Psychiatric Drugs</b> (Approved for use in other brain disorders)</p>
<p><b>Cholinesterase Inhibitors</b> (Increases signaling for essential cognitive functions)</p>	<p><b>Reduce Glutamate Signaling</b> (Lowers the frequency of certain neurotransmitters)</p>
<p><b>Other</b></p>	

Source: (1) ClinicalTrials.gov

## Selected Memory Care Companies

Most large skilled nursing and assisted living operators such as Brookdale Senior Living, NHC, and Sunrise Senior Living have memory care service lines, while other companies have a dedicated focus on memory care

	Company	Description	Selected Investors
Facilities Focused on Memory Care		Operator of 25 memory care and assisted living communities across 11 states. Most communities are focused on delivering care for individuals with Alzheimer’s disease and other dementias	Undisclosed
		Provider of assisted living and home care services for Alzheimer’s patients and senior citizens. Services include hospice care, care management, memory care assisted living, and in-home companion care. 28 locations across 10 states.	Welltower; Artemis Real Estate Partners
		Senior lifestyle community and home care provider offering independent living, assisted living, residential memory support, and non-residential community-based services.	Privately Held
Alternative Site Memory Care		Behavioral healthcare company focused on Alzheimer’s and other dementias. Empowers clinicians to adopt a new care model using disruptive technology to provide virtual care services to those experiencing cognitive decline.	ARCH Venture Partners; F-Prime Capital; General Catalyst; GV; 1843 Capital; Mass General Brigham Ventures; Rsquared; City Light Capital
		Professional home care services offering proprietary, specialized programs for those with Alzheimer’s and dementia, Parkinson’s and other chronic diseases. Franchises located across 42 states.	Advocate Aurora Enterprises

## Contact Us

Avondale Partners is an investment banking firm focused primarily on the healthcare services and healthcare technology sectors. Headquartered in Nashville, TN, we have completed over 200 transactions totaling more than \$40 billion in value. We differentiate ourselves by achieving superior outcomes for our clients through senior-level attention from bankers averaging more than 20 years of experience.

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