

Measuring Medicare and Total Societal Economic Impacts of a Potential Alzheimer's Disease Treatment for Medicare Beneficiaries (2022-2031)

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Presentation Overview

1. Analysis Highlights

2. Background

- Analytic Purpose
- Alzheimer's Disease Overview
- Therapeutic Goals of Potential AD Treatment

3. Methods

- Key Analytic Steps for Determining Potential Treatment Population
- "Where You Start Measuring Matters" (MCI versus Mild AD)
- Step Down Utilized to Find Final Annual Treatment Population
- Calculating the Delay of Disease Progression
- Estimating Other Annual Costs of MCI and AD

4. Findings

- Estimated Potential Treatment Population Savings – Impact over 10-Year Period (2022-2031)

5. Conclusion

Analysis Highlights

- The purpose of this analysis is to present potential savings from an innovative treatment for Alzheimer’s Disease (AD) as applied to the Medicare population over a ten-year time horizon, 2022-2031. The years 2020 and 2021 serve as a baseline for our 2022-2031 estimates. In 2020, 5.8 million Americans aged 65 and older (10%) were diagnosed with AD. The Alzheimer’s Disease Continuum consists of four stages: Mild Cognitive Impairment (MCI) due to AD, Mild AD, Moderate AD and Severe AD. Our study attributes savings to the first two stages of this continuum. This study was commissioned by Biogen, Inc.
- Our estimated cost savings assume the introduction of an AD medication that delays disease progression by six months for year 1, twelve months for year 2, eighteen months for year 3, and twenty-four months for all following years until 2031. We build upon a model of annual costs attributable to years before death (8.5 years)¹ and generate monthly totals to help better estimate potential savings. Our analysis uses the population remaining after this stepdown, ~5.5% of the initial 5.8 million patients. Then our analysis decreases the target population by 75% for incidence to target the people that would be entering the MCI & Mild AD four-year pool period each year. We assume a “take-up rate” that starts at 25% in 2022 and increases to 50% of a carefully determined population by 2031. After accounting for the take-up rate, this population is then 80,248 or ~1.4% of the initial population.

[1] Pyenson, B., Sawhney, T. G., Steffens, C., Rotter, D., Peschin, S., Scott, J., & Jenkins, E. (2019). The real-world Medicare costs of Alzheimer disease: Considerations for policy and care. *Journal of managed care & specialty pharmacy*, 25(7), 800-809.

Analysis Highlights cont.

- For Medicaid savings calculated with Medicare beneficiaries, we specifically focus on costs and savings generated from extended Nursing Home (NH) care. Our informal caregiving estimates also account for both a population that enrolls in nursing home care and a population that does not reside in a NH. Our total savings estimates for 10 years for each savings category's expenditures are shown in Table ES-1. Potential Direct Medicare savings are constrained since the Medicare expenditures (including Beneficiary copayments) associated with AD are ~11%¹ of total Medicare expenditures for AD patients. Our analysis found that greater savings are achieved through reductions in formal Medicaid and Non-Medicaid NH expenditures and informal caregiving and support expenditures. A drug that delays AD disease progression by two years promises significant social returns relative to drugs that extend life for much shorter time frames.

Exhibit ES-1: Estimated Potential Savings for Medicare AD Population

| Cost Category | Total 10-year Savings (2022-2031) |
|--|-----------------------------------|
| Medicare, including Beneficiary Copayments | \$1.24B |
| Medicaid and Non-Medicaid Nursing Home Costs | \$26.42B |
| Informal Care and Support Costs | \$11.86B |
| Total | \$39.52B |

Source: Dobson | DaVanzo Analysis

[1] Pyenson, B., Sawhney, T. G., Steffens, C., Rotter, D., Peschin, S., Scott, J., & Jenkins, E. (2019). The real-world Medicare costs of Alzheimer disease: Considerations for policy and care. *Journal of managed care & specialty pharmacy*, 25(7), 800-809.

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Analytic Purpose D/D Study

- Determine the cost saving impacts for Medicare, Medicaid and Informal Caregiving and Support expenditures associated with the clinical introduction of a Potential AD Treatment to the Medicare population.

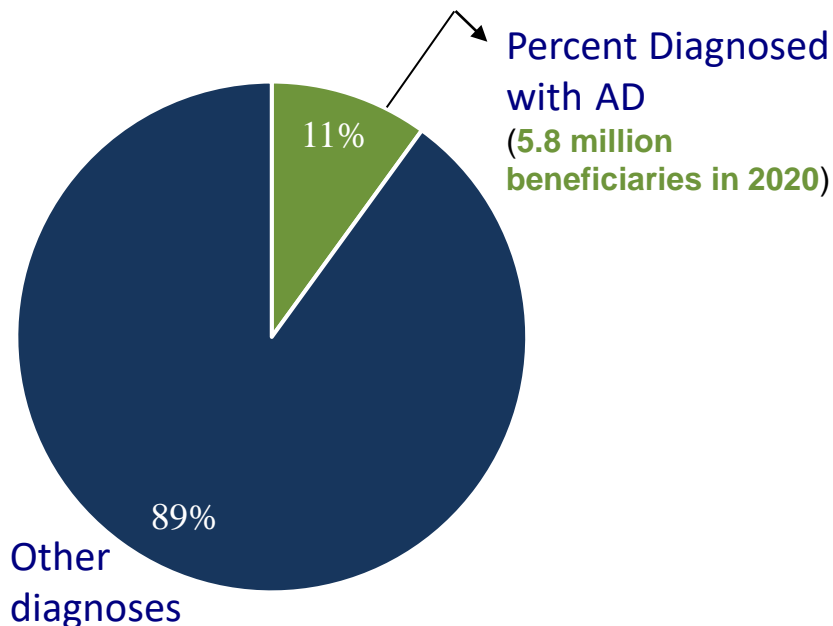
D/D Analytic Framework

- We present 10-year timeframe results, in order to better align with 10-year (2022-2031) CBO-type cost accounting methodology for estimating a Potential AD Treatment's impact.
- We focus specifically on the Medicare population.
- We do not account for the possible price for any potential AD drug or additional years of life, if any.
- We assume a delay in disease progression equivalent to six months for year 1, twelve months for year 2, eighteen months for year 3, and twenty-four months for all following years until 2031.
- For Medicare-only savings, reductions come from incremental healthcare expenditures for the Medicare population directly associated with AD. These savings were about ~11%¹ of total Medicare expenditures for each AD patient including Medicare Copayments.

[1] Pyenson, B., Sawhney, T. G., Steffens, C., Rotter, D., Peschin, S., Scott, J., & Jenkins, E. (2019). The real-world medicare costs of alzheimer disease: Considerations for policy and care. *Journal of managed care & specialty pharmacy*, 25(7), 800-809.

Alzheimer's Disease Overview

Percentage of Americans aged 65 and older diagnosed with Alzheimer's Disease¹



Source: Alzheimer's Association 2020 AD Facts and Figures

Healthcare costs for AD or Dementia among Medicare Beneficiaries 65 and older

- ▶ Formal Expenditures for Medicare Beneficiaries [including Medicare, Medicaid and Out-of-Pocket costs]
- ▶ Informal caregiving

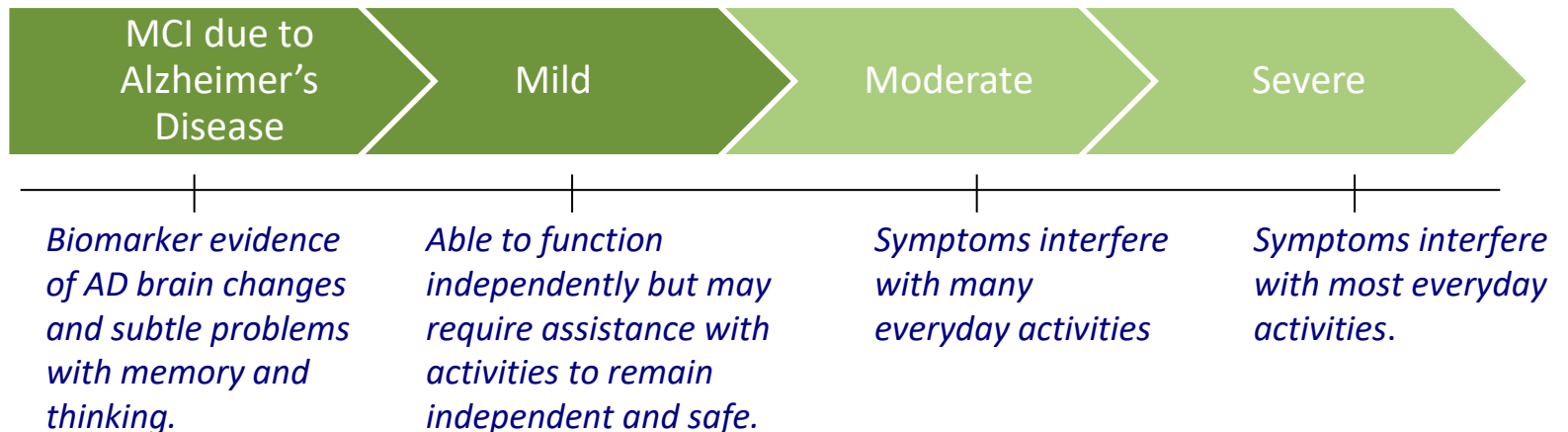
[1] Alzheimer's Association. (2020), 2020 Alzheimer's disease facts and figures. *Alzheimer's Dement.*, 16: 391-460. <https://doi.org/10.1002/alz.12068>

[2] Bruce Pyenson, Tia Goss Sawhney, Charles Steffens, David Rotter, Susan Peschin, James Scott, and Ellen Jenkins. "The Real-World Medicare Costs of Alzheimer Disease: Considerations for Policy and Care". *Journal of Managed Care & Specialty Pharmacy* 2019 25:7, 800-809

Alzheimer's Disease Overview cont.

Alzheimer's Disease Continuum

- Our Analysis focuses on Mild Cognitive Impairment (MCI) and Mild AD.
- Our Analysis assumes patients stay in the MCI and Mild AD stages of the patient journey for a total of four years.



Source: Dobson | DaVanzo Analysis

Therapeutic Goals of Potential AD Treatment

Advances in potential treatment for MCI due to AD and Mild AD:

- Since 2003, there have not been any novel medications approved for AD. There are no treatments currently on the market explicitly approved for early-stage AD patients.¹
- Biogen's potential AD treatment could impact the underlying disease pathophysiology, help preserve and extend AD patients' independence for longer, slow cognitive and functional decline, and possibly extend life expectancy.²

[1] McGinley L. Controversial Alzheimer's drug gets boost from FDA staff. Washington Post. 2020; <https://www.washingtonpost.com/health/2020/11/04/alzheimers-drug-fda/>

[2] Biogen Aducanumab One Pager from July 2020.

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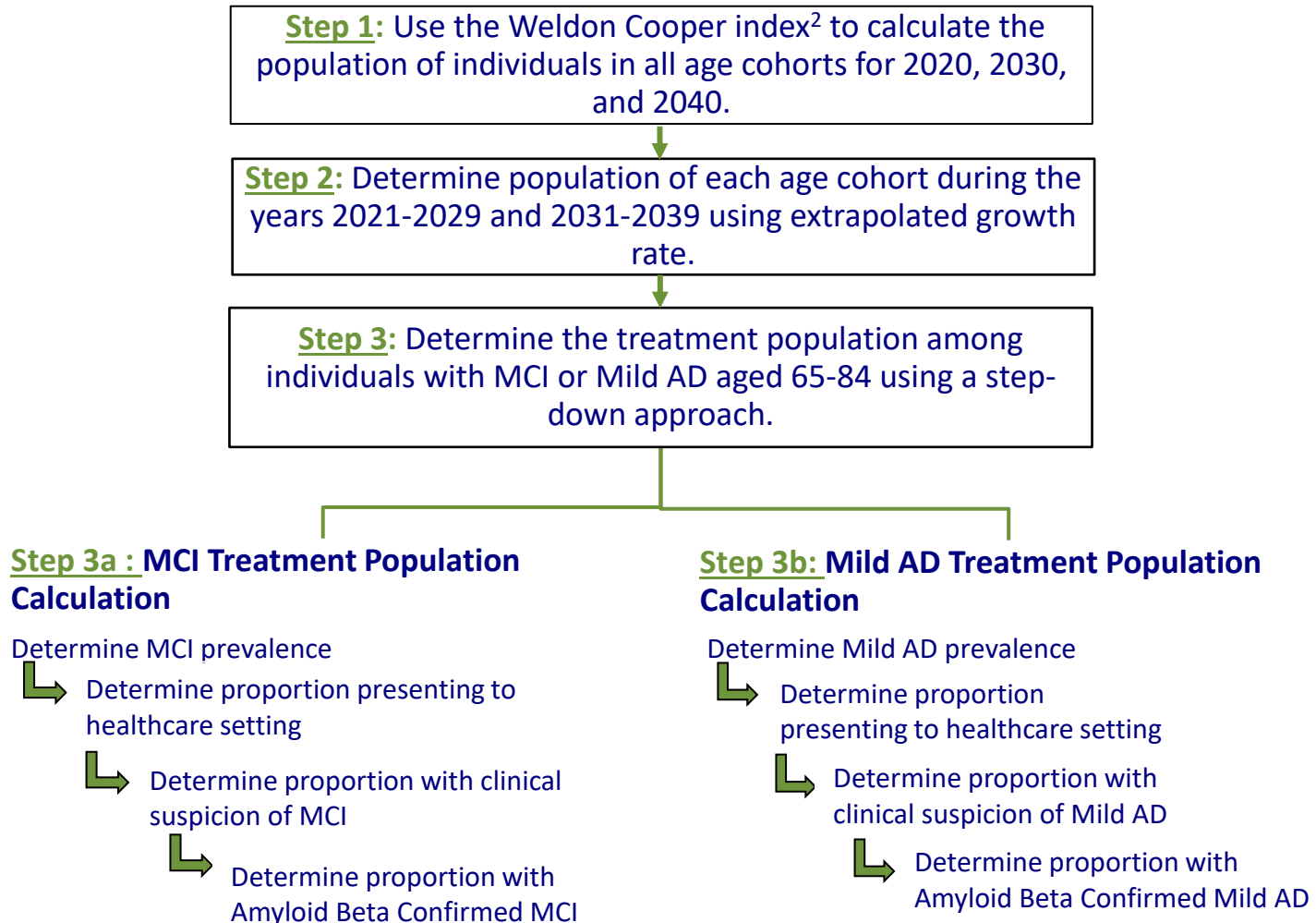
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Key Analytic Steps for Determining Potential Treatment Population¹



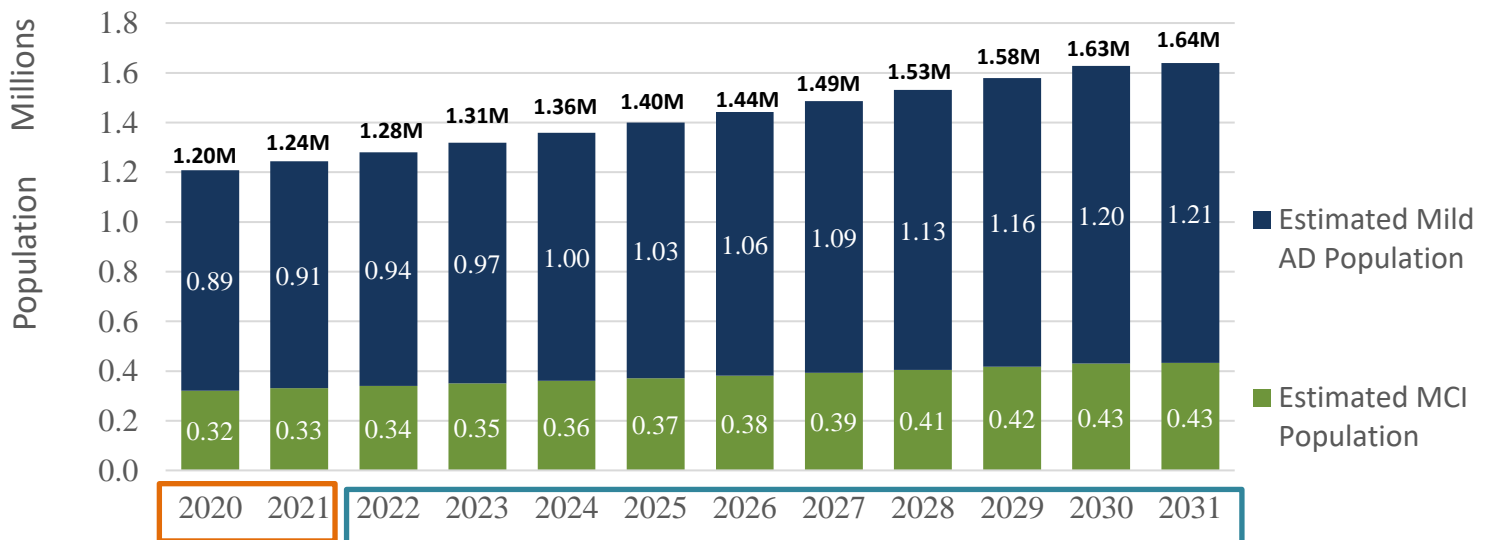
Source: Biogen Presentation 10/30/2020

[1] Derived from PowerPoint slides provided by Biogen Team on 10/30/2020.

[2] University of Virginia Weldon Cooper Center, Demographics Research Group. (2018). National Population Projections. Retrieved from <https://demographics.coopercenter.org/national-population-projections>

“Where You Start Measuring Matters” (MCI versus Mild AD)

D|D Estimates of MCI and Mild AD Treatment population



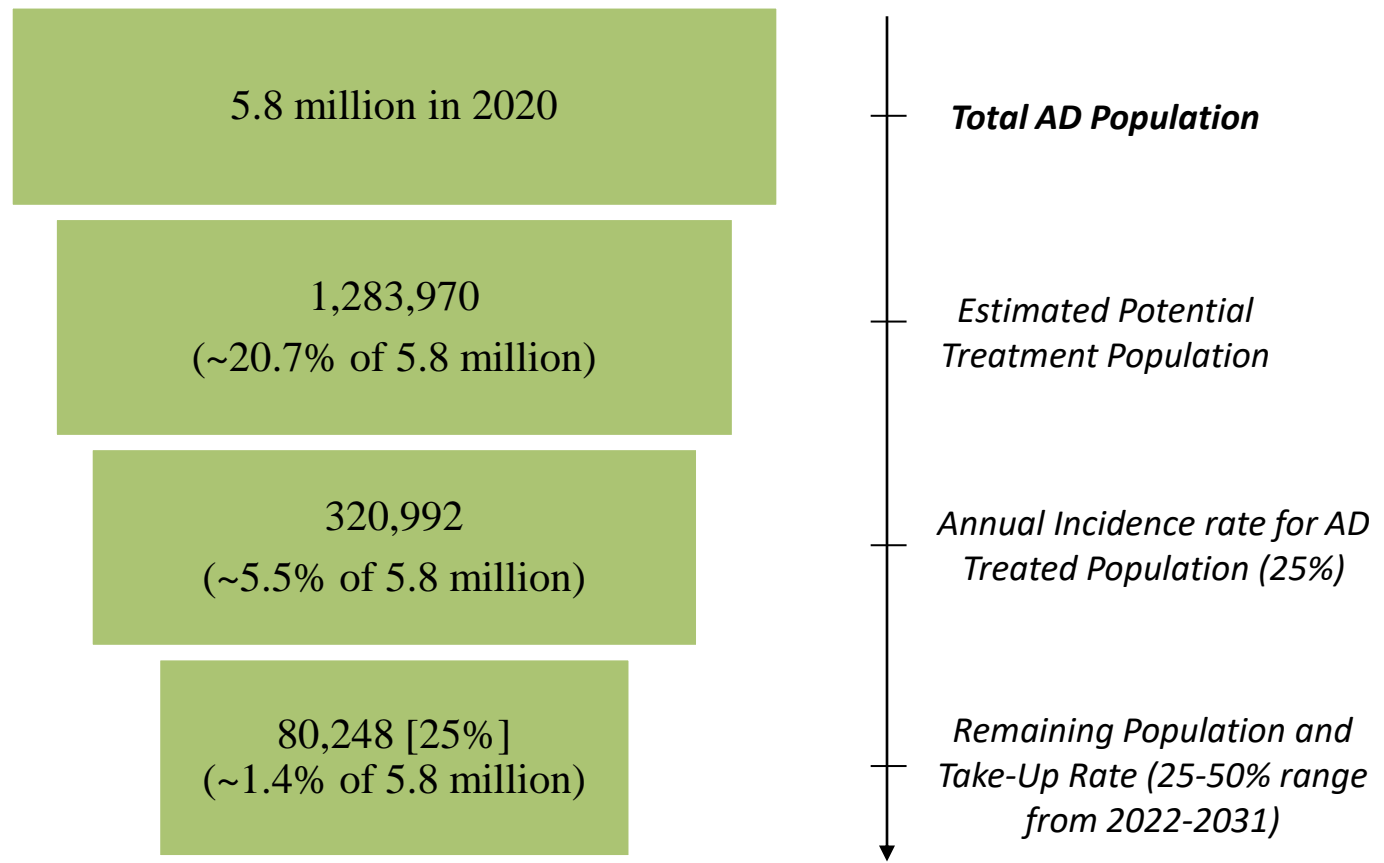
Source: Dobson | DaVanzo Analysis

- Specific targeting utilized in this analysis to early-stage AD (MCI and Mild AD) and those with Amyloid Beta clinical testing results leads to a limited target population. Baseline years are 2020 and 2021 while analysis years are 2022-2031.
- D|D’s estimate of total individuals with AD is comparable to Alzheimer’s Association’s estimate.¹

[1] Alzheimer’s Association. (2020), 2020 Alzheimer’s disease facts and figures. Alzheimer’s Dement., 16: 391-460. <https://doi.org/10.1002/alz.12068>

Step Down Utilized to Find Final Annual Treatment Population

Estimated Initial Treatment Population in 2022



Source: Dobson | DaVanzo Analysis

Step Down Utilized to Find Final Annual Treatment Population cont.

Projected Treatment Population in 2022-2031*

| Prevalence | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 |
|---------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Total MCI | 340,298 | 350,215 | 360,483 | 371,115 | 382,126 | 393,530 | 405,344 | 417,581 | 430,261 | 432,576 |
| Total Mild AD | 941,650 | 970,014 | 999,395 | 1,029,833 | 1,061,369 | 1,094,046 | 1,127,909 | 1,163,003 | 1,199,378 | 1,206,613 |
| Total MCI & Mild AD | 1,283,970 | 1,322,252 | 1,361,902 | 1,402,973 | 1,445,521 | 1,489,604 | 1,535,280 | 1,582,614 | 1,631,669 | 1,641,220 |

| MCI & Mild AD "Pool" | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 |
|-------------------------|---------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|----------------|
| Total MCI & Mild AD | 1,283,970 | 1,322,252 | 1,361,902 | 1,402,973 | 1,445,521 | 1,489,604 | 1,535,280 | 1,582,614 | 1,631,669 | 1,641,220 |
| "Pool" Percentage | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| "Pool" Incidence | 320,992 | 330,563 | 340,475 | 350,743 | 361,380 | 372,401 | 383,820 | 395,653 | 407,917 | 410,305 |
| Take-up Rate | 25% | 27% | 29% | 31% | 33% | 36% | 39% | 42% | 45% | 50% |
| Initial Users | 80,248 | 89,252 | 98,738 | 108,730 | 119,255 | 134,064 | 149,690 | 166,174 | 183,563 | 205,153 |
| Discontinuance (0%) | - | - | - | - | - | - | - | - | - | - |
| Study Population | 80,248 | 89,252 | 98,738 | 108,730 | 119,255 | 134,064 | 149,690 | 166,174 | 183,563 | 205,153 |

Source: Dobson | DaVanzo Analysis

*Note: Individuals in the MCI & Mild AD stages of the patient journey may initiate treatment, depending on diagnosis, presentation in health care settings, clinical suspicion of MCI or Mild AD, and Amyloid Beta Confirmation, as seen in our previous step-down chart.

Estimating Other Annual Costs of MCI and AD

- For our Medicaid estimates, our analysis focuses solely on the cost of Nursing Homes. This analysis follows the same delay model as for Medicare.
- We assume an average annual cost of Nursing Home care of ~\$82,125 or \$225 a day in 2022.¹ We inflate this using the CMS Market Basket Index for 2022-2031.
- In AD years 1-4, we assume that there is no utilization of NH care due to AD.
- Our analysis assumes 15% of the AD population live in nursing homes over the course of their patient journey.² A potential AD medication would reduce this percentage to 7.6% overall. The percentage of patients utilizing nursing home care steadily increases as a patient enters the last two stages of the patient journey (years 5-9).
- We assume that two-thirds of AD NH residents are entering NHs specifically due to AD.³

[1] Kaiser Family Foundation. Medicaid's Role in Nursing Home Care. Kaiser Family Foundation. 2017. <http://files.kff.org/attachment/Infographic-Medicoids-Role-in-Nursing-Home-Care>

[2] Chi W, Graf E, Hughes L, Hastie J, Khatutsky G, Shuman S, Jessup EA, Karon S, Lamont H. Older Adults with Dementia and Their Caregivers: Key Indicators from the National Health and Aging Trends Study. Washington, DC: The Office of the Assistant Secretary for Planning and Evaluation. 2019.

[3] Gaugler JE, Yu F, Davila HW, Shippee T. Alzheimer's disease and nursing homes. *Health Aff (Millwood)*. 2014 Apr;33(4):650-7. doi: 10.1377/hlthaff.2013.1268. PMID: 24711327; PMCID: PMC5767317.

Estimating Other Annual Costs of MCI and AD, cont.

- **For our informal caregiving and support cost estimates, we separated our population in the following ways:**
 - This analysis follows the same delay model as for Medicare. We utilize the same percentages of the AD population utilizing NH services shown on the previous slide.
 - Family involvement in the delivery of formal care provided by nursing homes includes “visiting, socioemotional care, advocacy, and the provision of personal care.”¹ Support provided while visiting is expansive and includes monitoring care, assisting professional staff with services, and communication facilitation.² Other support includes such contributions as laundry, errands, financial management.”³
 - Family involvement can be provided by more than one person. We assumed an average of total sixteen hours per week for the involvement of all family members for each nursing home resident with AD. This assumption was one-third of the assumed hours of informal care provided to community-dwelling individuals with comparable AD severity.
 - For AD patients, we assume that half of informal caregiving and support hours are associated with AD⁴.

[1] Joseph E. Gaugler. Family Involvement in Residential Long-Term Care: A Synthesis and Critical Review. *Aging & Mental Health*, 2005 March ; 9(2): 105–118.

[2] Amy Restorick Roberts, Karen J. Ishler, and Kathryn Betts Adams. The Predictors of and Motivations for Increased Family Involvement in Nursing Homes. *The Gerontologist*, 2020, Volume 60, No. 3, 535–547.

[3] Cynthia L. Port, Sheryl Zimmerman, Christianna S. Williams, Debra Dobbs, John S. Preisser, and Sharon Wallace Williams. Families Filling the Gap: Comparing Family Involvement for Assisted Living and Nursing Home Residents with Dementia. *The Gerontologist* 2005, Volume 45.

[4] Chi W, Graf E, Hughes L, Hastie J, Khatutsky G, Shuman S, Jessup EA, Karon S, Lamont H. Older Adults with Dementia and Their Caregivers: Key Indicators from the National Health and Aging Trends Study. Washington, DC: The Office of the Assistant Secretary for Planning and Evaluation. 2019.

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Estimated Potential Treatment Population Savings – Impact over 10-Year Period (2022-2031)

Potential 10-Year Savings for Medicare Treatment Population (2022 to 2031)

| Cost Category | D D Estimates –Impact of Delay Savings* |
|--|---|
| Medicare, including Beneficiary Copayments | \$1.24B |
| Medicaid (NH Care) | \$26.42B |
| Informal Care and Support Costs | \$11.86B |
| Total | \$39.52B |

Source: Dobson | DaVanzo Analysis

*Estimates do not consider any AD potential drug cost and additional years of life, if any.

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- Assessing Medicare Program healthcare cost savings understates the impact of effective AD treatment of Medicare beneficiaries due to broader societal expenditure burdens.
- Potential Medicare savings are limited because we focus only on those incremental costs directly associated with Medicare expenditures associated with AD.
- Savings estimates are primarily achieved through reductions in Medicaid NH expenditures and informal caregiving and support expenditures.
- “Where you start measuring” a potential treatment population within the AD population makes a difference. We start with a population of 5.8 million AD patients and only include savings on a treatment population of 80,248 or approximately 1.4% of the initial 5.8 million population. By 2031, we assume a total treatment population of 205,153.
- The most important benefit of the potential AD treatment is likely not monetary, but rather quality of life due to a delay in the debilitating aspects of AD.
- A drug that delays AD disease progression by two years promises significant social returns relative to drugs that extend life for much shorter time frames.



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