Opportunities to Optimize Management and Care for People with Dementia

Shari Ling, MD
Deputy Chief Medical Officer
Centers for Medicare & Medicaid Services
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Vision: What’s to Come Over the Next 10 Years

A Health System that Achieves Equitable Outcomes through High Quality, Affordable, Person-Centered Care

Drive Accountable Care
Advance Health Equity
Support Innovation
Address Affordability
Partner to Achieve System Transformation

To read the white paper, visit innovation.cms.gov
Percentage of Medicare FFS Beneficiaries with Selected Chronic Conditions: 2018

Source: CMS Chronic Conditions Chartbook 2018


Alzheimer’s Disease Disparities in Medicare Fee-For-Service Beneficiaries

Dementia is an umbrella term for a wide range of progressive brain diseases that are characterized by the onset of behavioral, cognitive, and emotional impairments primarily in older adults. The most common form of dementia is Alzheimer’s disease, which slowly destroys memory and thinking skills until an individual can no longer perform even the simplest tasks of daily living. There is currently no cure for Alzheimer’s disease, no definitive cause, and no single test factor in aging. According to Centers for Disease Control and Prevention (CDC), there were 14 million Americans living with Alzheimer’s disease in 2020 but, it is noted, that number is projected to rise to 14 million partly due to the aging of the U.S. population. Alzheimer’s Disease is the third-leading cause of death among adults age 65 years or older.

Data from the Centenarian Medicare & Medicaid Services (CMS) Chronic Conditions Data Warehouse indicates that about 51% of all Medicare fee-for-service (FFS) beneficiaries had claims with a diagnosis of Alzheimer’s disease or related dementia, and 4% of the beneficiaries had Alzheimer’s disease in 2020.

The Mapping Medicare Disparities (MMD) tool developed by CMS Office of Minority Health shows the prevalence of Alzheimer’s disease or a related dementia among Medicare FFS beneficiaries varied by age, sex, race and ethnicity, eligibility for Medicare, and geographic areas in 2020. The beneficiaries eligible for both Medicare and Medicaid had a higher prevalence rate (7%) than those with Medicare only (6%). The age-standardized prevalence rate of Alzheimer’s disease or a related dementia among Black/African American beneficiaries (13%) was higher than other racial/ethnic groups, and the lowest rates were observed in the Asian/Pacific Islanders and White beneficiaries (10%) as shown in Figure 1. The prevalence was higher among older beneficiaries as shown in Figure 2. More than one-third of beneficiaries aged 65 and older had claims with a diagnosis of Alzheimer’s disease or a related dementia while only 4% of beneficiaries aged 65

CMS Data Snapshot:
Alzheimer’s Disease

CMS Strategic Plan Pillar: Health Equity
CMS Services That Support People with Serious Illness & Dementia

**Medicare**
- Behavioral Health Integration
- Chronic Care Management
- Complex Chronic Care Management
- Cognitive Impairment Assessment
- Caregiver assessment
- Advance Care Planning
- Annual Wellness Visit and Welcome to Medicare
- Group and Individual Counseling
- Psychotherapy
- Psychiatric Collaborative Care and Behavioral Health Integration
- Home Health
- Hospital
- Short-term Nursing Home Care
- Hospice
- Telehealth service delivery
- Durable Medical Equipment
- Transitional care management
- PT/OT/Speech therapies
- (Supplemental benefits – MAOs)

**Medicaid**
- Home and Community-Based Services
- Health Homes
- Targeted Case Management
- Home Health
- Rehabilitative Services
- Program for All-Inclusive Care (PACE)
- Hospital
- Short and Long-Term Nursing Home Care
- Hospice
- Telehealth service delivery
- Medical equipment and supplies
- PT/OT/Speech therapies

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**Medicare Coverage of Cognitive Assessment & Care Plan Services – CPT Code 99483**

- Providers may perform a cognitive assessment during a visit (including the yearly “Wellness” visit) to look for signs of dementia, including Alzheimer’s disease.
- Medicare Part B (Medical Insurance) also covers a separate visit with the person’s regular doctor or a specialist to fully review cognitive function, establish or confirm a diagnosis like dementia (including Alzheimer’s disease), and establish a care plan.
- In Original Medicare, a person pays 20% of the Medicare-Approved Amount after the person meets the annual Part B deductible amount.


Evidence-Based Medicare Coverage

Medicare coverage determinations address whether the evidence is sufficient to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population.
  » Age ≥ 65 years
  » Some disabled individuals
  » People with end stage renal disease and ALS

https://www.cms.gov/Medicare/Coverage/DeterminationProcess

National Coverage Determinations (NCD)

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- NCDs are made through an evidence-based process, with opportunities for public participation.

https://www.cms.gov/Medicare/Coverage/DeterminationProcess
National Coverage Determination for Monoclonal Antibodies (mAbs) Directed Against Amyloid for the Treatment of Alzheimer’s Disease (AD)

- On April 7, 2022, CMS announced a final Medicare NCD that covers FDA approved mAbs directed against amyloid for the treatment of AD when furnished in accordance to the coverage criteria specified under CED for patients who have a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.

- The NCD creates a predictable pathway to Medicare coverage for anti-amyloid mAbs that are approved by the FDA through the approval pathway using:
  - Surrogate endpoints (e.g., amyloid reduction) considered reasonably likely to predict clinical benefit; and
  - Direct measures of clinical benefit

- Anti-amyloid mAbs approved by the FDA using
  - Surrogate endpoints considered reasonably likely to predict clinical benefit may be covered in a randomized controlled trial conducted under an investigational new drug application.
  - Direct measures of clinical benefit may be covered in CMS approved prospective comparative studies. The NCD allows flexibility in study designs to include a registry with a comparison group.

- To read the final NCD CED decision memorandum visit:

Medicaid Coverage of mAbs Directed at Amyloid Reduction

- **Full Dually Eligible**: For purposes of this NCD, when Aduhelm or other drugs included in the NCD are non-covered by Medicare Part B under the terms of the NCD, CMS considers them Part D drugs. Medicaid does not pay for Part D drugs for full-benefit dually eligible individuals, regardless of whether they are enrolled in a Part D plan.
  - This means that when the drugs included in the NCD are non-covered by Part B under the terms of the NCD, regardless of whether a full-benefit dually eligible individual’s Part D plan actually covers the drug, Medicaid will not cover them.

- **Non Full Dually Eligible**: Generally, states are required to cover the drug if the manufacturer has in effect a National Drug Rebate Agreement with HHS and when the drug is used for a medically accepted indication, subject to any permissible restrictions or limitations on coverage applied by the state (e.g., prior authorization). Because the manufacturer of Aduhelm has entered into and has in effect a Medicaid drug rebate agreement and because Aduhelm also satisfies the definition of a covered outpatient drug, as set forth at section 1927(k)(2) of the Social Security Act (Act), state Medicaid programs are required to cover the drug when used for a medically accepted indication.
  - State Medicaid programs could subject Aduhelm to utilization management techniques, such as prior authorization, and medical necessity criteria. As a covered outpatient drug, states may invoice the manufacturer for rebates on the drug, and manufacturers would be required to pay rebates, as appropriate, when dispensed and paid for under the State plan.
Medicare Clinical Laboratory Fee Schedule (CLFS) Payment

- Medicare Part B, which includes a variety of outpatient services, covers medically necessary clinical diagnostic laboratory tests when a doctor or other practitioner orders them.
- CMS is required to set a payment rate for any “new or revised HCPCS code.” – does not mean covered
- Payment rates are determined via crosswalk or gapfill methodologies during an annual public meeting process
  - A new test must have a HCPCS code and be presented at the CMS Annual Public Laboratory Meeting
    [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings)
- Payments are reset every three years under Protecting Access to Medicare Act of 2014 (PAMA)
- Requires private payer rates paid to applicable laboratories for clinical diagnostic laboratory tests to be reported to CMS and used to calculate Medicare payment rates.
  - Medicare payment amounts for clinical diagnostic laboratory tests are based on this data beginning January 1, 2018.
- Questions: [CLFS_Inquiries@cms.hhs.gov](mailto:CLFS_Inquiries@cms.hhs.gov)

Advanced Diagnostic Laboratory Test (ADLT) Criteria & Payment

- **Some tests are eligible to apply as Advanced Diagnostic Laboratory tests (ADLT)** To qualify, the test must meet these criteria:
  - Medicare Part B covers it
  - A single laboratory offers and provides the test
  - The single laboratory (or a successor owner) sells it exclusively
- **ADLTs must also meet 1 of the following criteria:**
  - U.S. FDA clears or approves the test
  - The test meets all the following criteria:
    - Provides an analysis of multiple DNA, RNA, or protein biomarkers combined with a unique algorithm to yield a single patient-specific result.
    - The test is cleared or approved by the FDA.

Note: Biomakers fall under ADLT
Health Outcomes of Interest for the Medicare Population

**More Definitive**
- Longer life and improved function/participation
- Longer life with arrested decline
- Significant symptom improvement allowing better function/participation
- Reduced need for burdensome tests and treatments

**Less Definitive**
- Longer life with declining function/participation
- Improved disease-specific survival without improved overall survival
- Surrogate test result better
- Image looks better
- Clinician feels confident

*Medicare has stated publicly that as a matter of policy that it does not generally consider cost in making national coverage determinations.*

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Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014

- Bill passed on September 18, 2014, and signed into law October 6, 2014
- **The Act requires the submission of standardized patient assessment data elements by:**
  - Long-Term Care Hospitals (LTCHs): LCDS
  - Skilled Nursing Facilities (SNFs): MDS
  - Home Health Agencies (HHAs): OASIS
  - Inpatient Rehabilitation Facilities (IRFs): IRF-PAI
- **The Act specifies that data “... be standardized and interoperable so as to allow for the exchange of such data among such post-acute care providers and other providers and the use by such providers of such data that has been so exchanged, including by using common standards and definitions in order to provide access to longitudinal information for such providers to facilitate coordinated care and improved Medicare beneficiary outcomes...”**

*Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014*
Post-acute Care Assessment Content

**Administrative Content**
- Patient Name
- Date of Birth
- Race/Ethnicity
- Marital status
- Admission/Discharge dates
- Admit from/Discharged to locations
- Reason for admission
- Provider NPI, CCN, Medicaid Provider #

**“SPADEs”**
- Function (e.g., self care and mobility)
- Cognitive function (e.g., express & understand ideas; mental status, such as depression and dementia)
- Special services, treatments & interventions (e.g., need for ventilator, dialysis, chemotherapy, and total parenteral nutrition)
- Medical conditions and co-morbidities (e.g., diabetes, heart failure, and pressure ulcers)
- Impairments (e.g., incontinence; impaired ability to hear, see, or swallow)
- Other categories

**Clinical Content**
- Diagnosis/medical conditions
- Mental/Cognitive Status (memory, orientation, consciousness, delirium, mood, behavior)
- Communication (express needs, understanding verbal/non-verbal content, hearing and vision)
- Functional Status (Self-care/ADLs, Mobility, Use of assistive devices)
- Bladder and Bowel continence
- Falls
- Pressure ulcers and other skin conditions
- Surgery
- Nutritional and swallowing status
- Medication information
- Special treatments, procedures & programs
- Weight
- Height
- Patient preferences and goals of treatment
- Pain
- Vaccinations
- Therapy: PT, OT, SLT
- Living arrangements/support availability
- Care planning

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The CMS Data Element Library: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014

Visit the DEL here: [https://del.cms.gov](https://del.cms.gov)
### Current Cognitive Impairment Quality Measures

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Program</th>
<th>Steward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia: Cognitive Assessment</td>
<td>Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>American Academy of Neurology (AAN)</td>
</tr>
<tr>
<td>Dementia: Education and Support of Caregivers for Patients with Dementia</td>
<td>Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>AAN/American Psychiatric Association (APA)</td>
</tr>
<tr>
<td>Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia</td>
<td>Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concern screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>AAN/APA</td>
</tr>
<tr>
<td>Dementia: Functional Status Assessment</td>
<td>Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>AAN/APA</td>
</tr>
<tr>
<td>Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management</td>
<td>Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>AAN/APA</td>
</tr>
<tr>
<td>Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson’s Disease</td>
<td>Percentage of all patients with a diagnosis of Parkinson’s Disease who were assessed for cognitive impairment or dysfunction once during the measurement period.</td>
<td>MIPS; Doctors and Clinicians Compare</td>
<td>AAN</td>
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### Current Quality Measures, continued

<table>
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<tr>
<td>Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs</td>
<td>Rate of risk-standardized acute, unplanned hospital admissions among Medicare fee-for-service (FFS) patients 65 years and older with multiple chronic conditions (MCCs). [One of the groups of chronic conditions included is: Alzheimer’s disease and related disorders or senile dementia]</td>
<td>Medicare Shared Savings Program</td>
<td>Centers for Medicare &amp; Medicaid Services (CMS)</td>
</tr>
<tr>
<td>Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions for MIPS</td>
<td>Annual risk-standardized rate of acute, unplanned hospital admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with multiple chronic conditions (MCCs). [One of the groups of chronic conditions included is: Alzheimer’s disease and related disorders or senile dementia]</td>
<td>MIPS</td>
<td>CMS</td>
</tr>
<tr>
<td>Follow-up after Emergency Department (ED) Visit for Patients with Multiple Chronic Conditions</td>
<td>Percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following chronic conditions: COPD; Alzheimer’s disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.</td>
<td>Medicare Part C Star Rating/Medicare Advantage Quality Improvement Program/ HEDIS Quality Measure Rating System</td>
<td>CMS</td>
</tr>
<tr>
<td>30-day all-cause unplanned readmission following psychiatric hospitalization in an inpatient psychiatric facility (IPF)</td>
<td>This facility-level measure estimates an unplanned, 30-day, risk-standardized readmission rate for adult Medicare fee-for-service (FFS) patients with a principal discharge diagnosis of a psychiatric disorder or dementia/Alzheimer’s disease.</td>
<td>Inpatient Psychiatric Facility Quality Reporting/ Hospital Compare</td>
<td>CMS</td>
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</table>
- There has been an evolution in how we furnish care to people with dementia

- The process across detection, diagnosis, assessment of risk factors, and care management should be seamless

- Comorbidities matter

Shari.Ling@cms.hhs.gov