

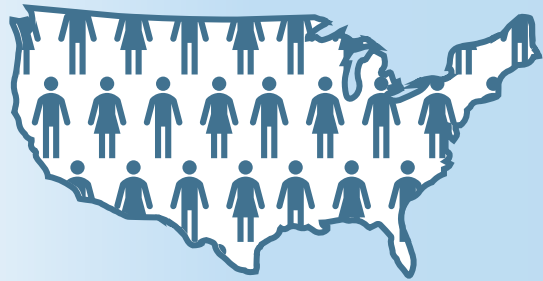


# Agitation Associated With Alzheimer's Dementia (AAD) in the Long-Term Care (LTC) Setting

This program is paid for by Otsuka  
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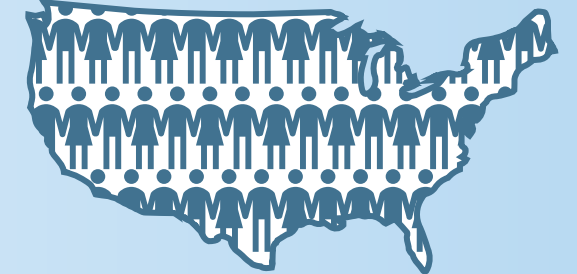
# Alzheimer's Dementia Is a Highly Prevalent Neurodegenerative Disorder<sup>1</sup>

Estimated number of US adults aged  $\geq 65$  years living with Alzheimer's dementia:



2023  
~6.7  
MILLION

2050  
~12.7  
MILLION



**75%** of people with Alzheimer's dementia aged  $\geq 80$  years old live in a LTC facility, compared with **4%** of the general population

LTC, long-term care. US, United States.

1. Alzheimer's Association 2023. Alzheimers Dement. 2023;19(4):1598-1695.

# Disease State Overview of Agitation Associated With Alzheimer's Dementia (AAD)

Agitation is one of the most common neuropsychiatric symptoms of Alzheimer's dementia<sup>1</sup>

- Manifestations of Alzheimer's dementia are not limited to cognitive decline and functional impairment, and include a range of neuropsychiatric symptoms, such as anxiety, irritability, and agitation<sup>2-5</sup>
- Symptoms of agitation manifest as both non-aggressive and aggressive behaviors, such as<sup>6,7</sup>:

## EXCESSIVE MOTOR ACTIVITY:

Pacing, restlessness, repetitiveness, and hoarding



## VERBAL AGGRESSION:

Screaming, using profanity, and asking repetitive questions

## PHYSICAL AGGRESSION:

Hitting, kicking, punching, biting, and throwing things

1. Halpern R, et al. Int J Geriatr Psychiatry. 2019;34(3):420-431.

2. Alzheimer's Association 2023. Alzheimers Dement. 2023;19(4):1598-1695.

3. Antonsdottir IM, et al. Expert Opin Pharmacother. 2015;16(11):1649-1656.

4. Anatchkova M, et al. Int Psychogeriatr. 2019;31(9):1305-1318.

5. Kales HC, et al. BMJ. 2015;350:h369.

6. Sano M, et al. Int Psychogeriatr. 2023;1-13.

7. Rabinowitz J, et al. Am J Geriatr Psychiatry. 2005;13(11):991-998.

# Agitation Is One of the Most Complex, Prominent, Stressful, and Costly Aspects of Alzheimer's Dementia Care<sup>1</sup>

Agitation can be present at any stage of Alzheimer's dementia<sup>2</sup>

However, it is most often recognized in the moderate-severe and severe stages of Alzheimer's dementia<sup>2</sup>



Agitation in Alzheimer's dementia is a common cause of placement in LTC<sup>3</sup>

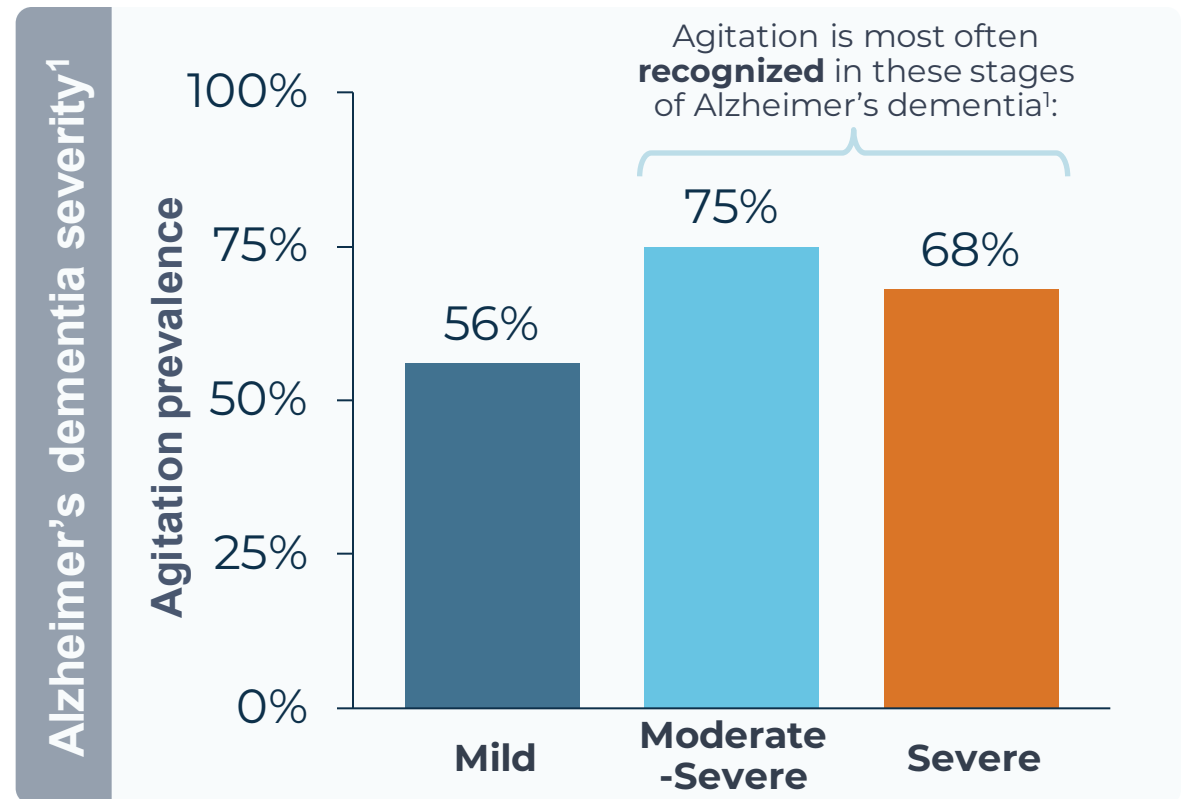
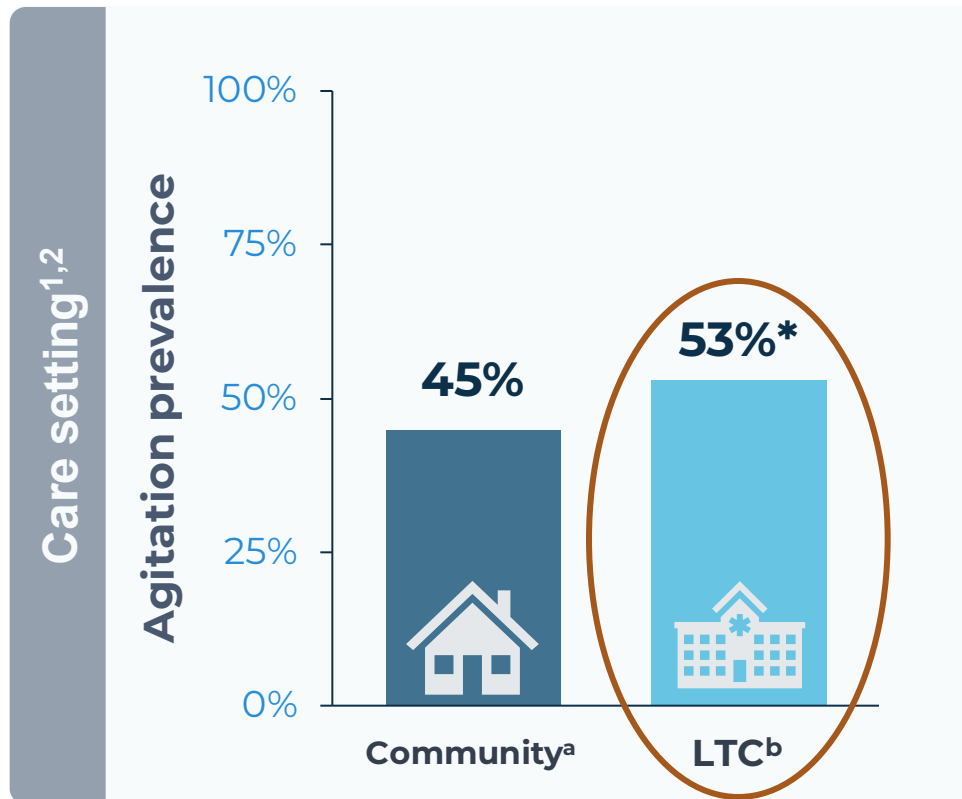


LTC, long-term care.

1. Antonsdottir IM, et al. Expert Opin Pharmacother. 2015;16(11):1649-1656.
2. Halpern R, et al. Int J Geriatr Psychiatry. 2019;34(3):420-431.
3. Cloutier M, et al. Alzheimers Dement (NY). 2019;5:851-861.

# Prevalence of Agitation Associated With Alzheimer's Dementia (AAD)

AAD is prevalent across care settings and Alzheimer's dementia severities<sup>1,2</sup>



\*Nursing home percentage reported includes those with Alzheimer's dementia and other dementias. aResidential homes. bNursing homes/skilled nursing facilities.

AAD, agitation associated with Alzheimer's dementia. LTC, long-term care.

1. Halpern R, et al. Int J Geriatr Psychiatry. 2019;34(3):420-431.

2. Fillit H, et al. Int J Geriatr Psychiatry. 2021;36(12):1959-1969.

# The Four IPA Criteria Offer a Solid Foundation for Recognition of Agitation in Cognitive Disorders<sup>1,2</sup>

1. The IPA definition of agitation in cognitive disorders includes four criteria:
2. The patient meets the criteria for cognitive impairment or dementia syndrome
3. The patient exhibit  $\geq 1$  agitation behavior(s) with emotional duress that is persistent or frequently recurrent for  $\geq 2$  weeks or the behavior represents a dramatic change from the patient's usual behavior\*
4. The behaviors are severe and associated with excess distress or produce disability beyond that due to cognitive impairment
5. The behaviors cannot be attributed to another psychiatric disorder, medical condition, including delirium, suboptimal care conditions, or the physiological effects of a substance

## Agitation behaviors include:



### EXCESSIVE MOTOR ACTIVITY BEHAVIORS:

- Pacing
- Rocking
- Gesturing
- Pointing fingers
- Restlessness
- Performing repetitious mannerisms



### VERBAL AGGRESSION BEHAVIORS:

- Yelling
- Speaking in an excessively loud voice
- Using profanity
- Screaming
- Shouting



### PHYSICAL AGGRESSION BEHAVIORS:

- Grabbing
- Shoving
- Pushing
- Resisting
- Hitting others
- Kicking objects or people
- Scratching
- Biting
- Throwing objects
- Hitting self
- Slamming doors
- Tearing things
- Destroying property

\*In special circumstances, the ability to document the behaviors over 2 weeks may not be possible and other terms of persistence and severity may be needed to capture the syndrome beyond a single episode.  
IPA, International Psychogeriatric Association.

1. Sano M, et al. Int Psychogeriatr. 2023;1-13.
2. Cummings J, et al. Int Psychogeriatr. 2015;27(1):7-17.

# The CMAI Measures a Broad Range of Behaviors of Agitation Consistent With the IPA Definition of Agitation<sup>1,2</sup>



**EXCESSIVE MOTOR ACTIVITY**



**VERBAL AGGRESSION**



**PHYSICAL AGGRESSION**



**OTHER BEHAVIORS**

| 29 CMAI behaviors <sup>2,3</sup>    |  |                                       |   |  |
|-------------------------------------|--|---------------------------------------|---|--|
| Pacing and aimless wandering        | Hiding things  | Throwing things                       | Spitting                                  | Making physical sexual advances or exposing genitals |
| Inappropriate dressing or disrobing | Hoarding things  | Screaming                             | Cursing or verbal aggression              | Eating or drinking inappropriate substances          |
| Trying to get to a different place  | Constant unwarranted request for attention and/or help | Biting                                | Hitting self or others                    | Making strange noises                                |
| Handling things inappropriately     | Repetitive sentences and questions                     | Scratching                            | Kicking                                   | Intentional falling                                  |
| Performing repetitious mannerisms   | Complaining  | Hurting self or others                | Grabbing people or things inappropriately | Making verbal sexual advances                        |
| General restlessness                | Negativism   | Tearing things or destroying property | Pushing                                   |  |



Many behaviors in the CMAI are relevant to the three domains of the IPA definition of agitation, including<sup>1,2</sup>:

CMAI, Cohen-Mansfield Agitation Inventory. IPA, International Psychogeriatric Association.

1. Cummings J, et al. *Int Psychogeriatr*. 2015;27(1):7-17.
2. Cohen-Mansfield J. *Instruction Manual for the Cohen-Mansfield Agitation Inventory (CMAI)*. 1991. Rockville, MD: Research Institute of the Hebrew Home of Greater Washington.
3. Rabinowitz J, et al. *Am J Geriatr Psychiatry*. 2005;13(11):991-998.

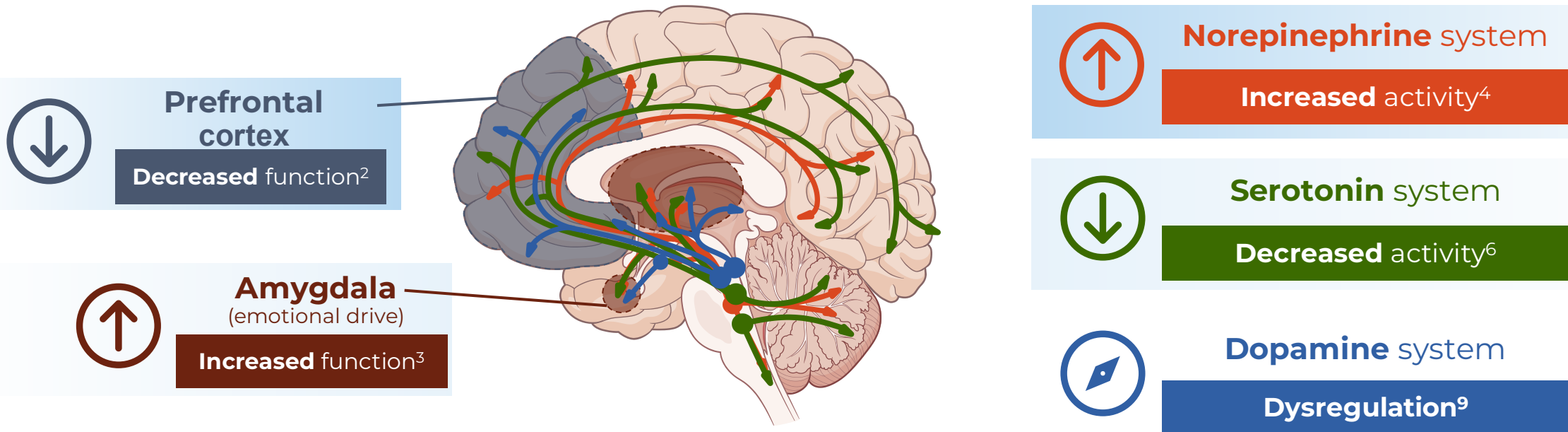


# Summary of Brain Pathology and Monoaminergic Dysfunction in AAD

Tau pathology and neurodegeneration in prefrontal and subcortical brain regions may increase the risk of developing AAD<sup>1</sup>

AAD may reflect an imbalance between top-down **executive control** and bottom-up **emotional drive**<sup>1</sup>

Dysfunction of NSD neurotransmitter system may contribute to imbalance between **executive control** and **emotional overdrive**<sup>2-10</sup>



AAD, agitation associated with Alzheimer's dementia. NSD, norepinephrine-serotonin-dopamine.

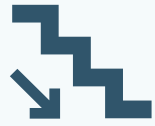
- Rosenberg PB, et al. *Mol Aspects Med.* 2015;43-44:25-37.
- Banno K, et al. *Neuropsychiatr Dis Treat.* 2014;10:339-348.
- Wright CI, et al. *Biol Psychiatry.* 2007;62(12):1388-1395.
- Jacobs HI, et al. *Mol Psychiatry.* 2021;26(3):897-906.
- Arnsten AF, et al. *Neurobiol Stress.* 2015;1:89-99.
- Lancôt KL, et al. *J Neuropsychiatry Clin Neurosci.* 2001;13(1):5-21.
- Evers EA, et al. *Curr Pharm Des.* 2010;16(18):1998-2011.
- Duke AA, et al. *Psychol Bull.* 2013;139(5):1148.
- Cox SM, et al. *Br J Psychiatry.* 2011;199(5):391-397.
- Lindenmayer JP. *J Clin Psychiatry.* 2000;61(14):5-10.

# AAD Worsens the Impact of an Already Devastating and Burdensome Disease<sup>1,2</sup>

Overall, agitation versus no agitation in patients with Alzheimer's dementia been associated with<sup>1-7</sup>:



Accelerated disease progression



Functional decline



Decreased quality of life



Greater comorbidities



Increased use of concomitant therapies



Earlier death



Increased risk of hospitalization/institutionalization

In the **LTC** setting, agitation versus no agitation has been associated with a significantly **increased risk** of<sup>1</sup>:



Falls



Fractures



Infections



Higher medication use



Other NPS<sup>a</sup>

aIncludes depression, anxiety, delusion, and hallucinations.

AAD, agitation associated with Alzheimer's dementia. LTC, long-term care. NPS, neuropsychiatric symptoms.

1. Fillit H, et al. Int J Geriatr Psychiatry. 2021;36(12):1959-1969. 2.

2. Jones E, et al. J Alzheimers Dis. 2021;83(1):89-101. 3.

3. Halpern R, et al. Int J Geriatr Psychiatry. 2019;34(3):420-431. 4.

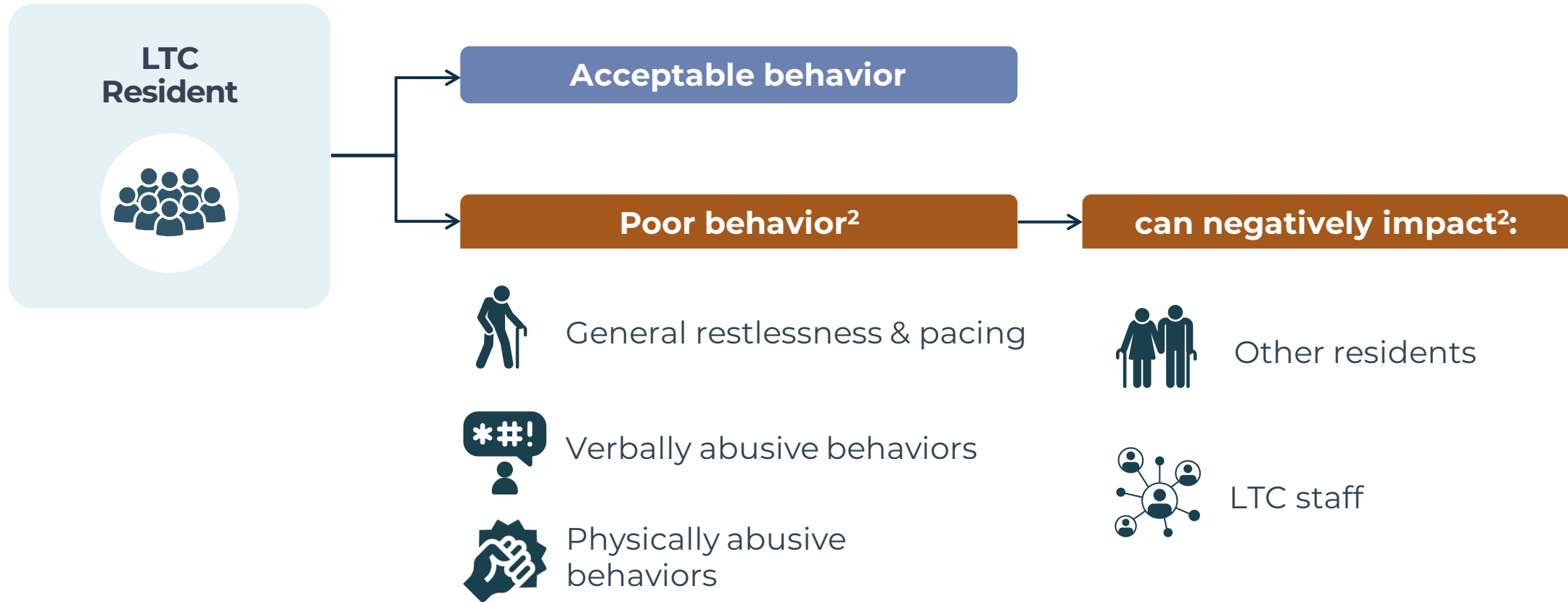
4. Koenig AM, et al. Curr Psychiatry Rep. 2016;18(1):3. 5.

5. Peters ME, et al. Am J Psychiatry. 2015;172(5):460-465. 6.

6. Scarmeas N, et al. Arch Neurol. 2007;64(12):1755-1761.

7. Banerjee S, et al. J Neurol Neurosurg Psychiatry. 2006;77(2):146-148.

# The Level of Disruptiveness of Agitated Behaviors Increases With Frequency for All Types of Behavior<sup>1,a</sup>



<sup>a</sup>Measured using the CMAI.

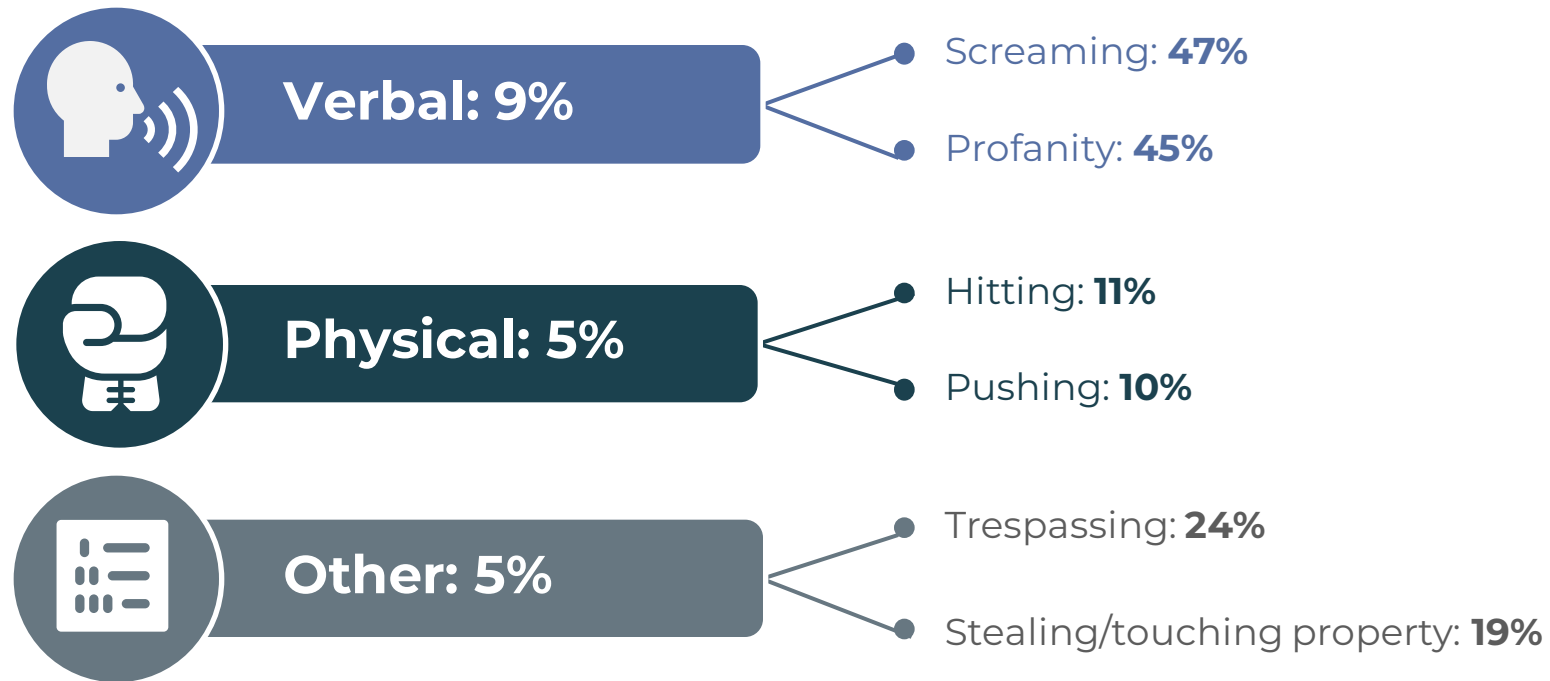
CMAI, Cohen-Mansfield Agitation Inventory. LTC, long-term care.

1. Cohen-Mansfield J. *J Psychiatr Res.* 2008;43(1):64-69.

2. Fillit H, et al. *Int J Geriatr Psychiatry.* 2021;36(12):1959-1969.

# Resident-to-Resident Mistreatment in the LTC Setting Is a Large and Pervasive Problem<sup>1</sup>

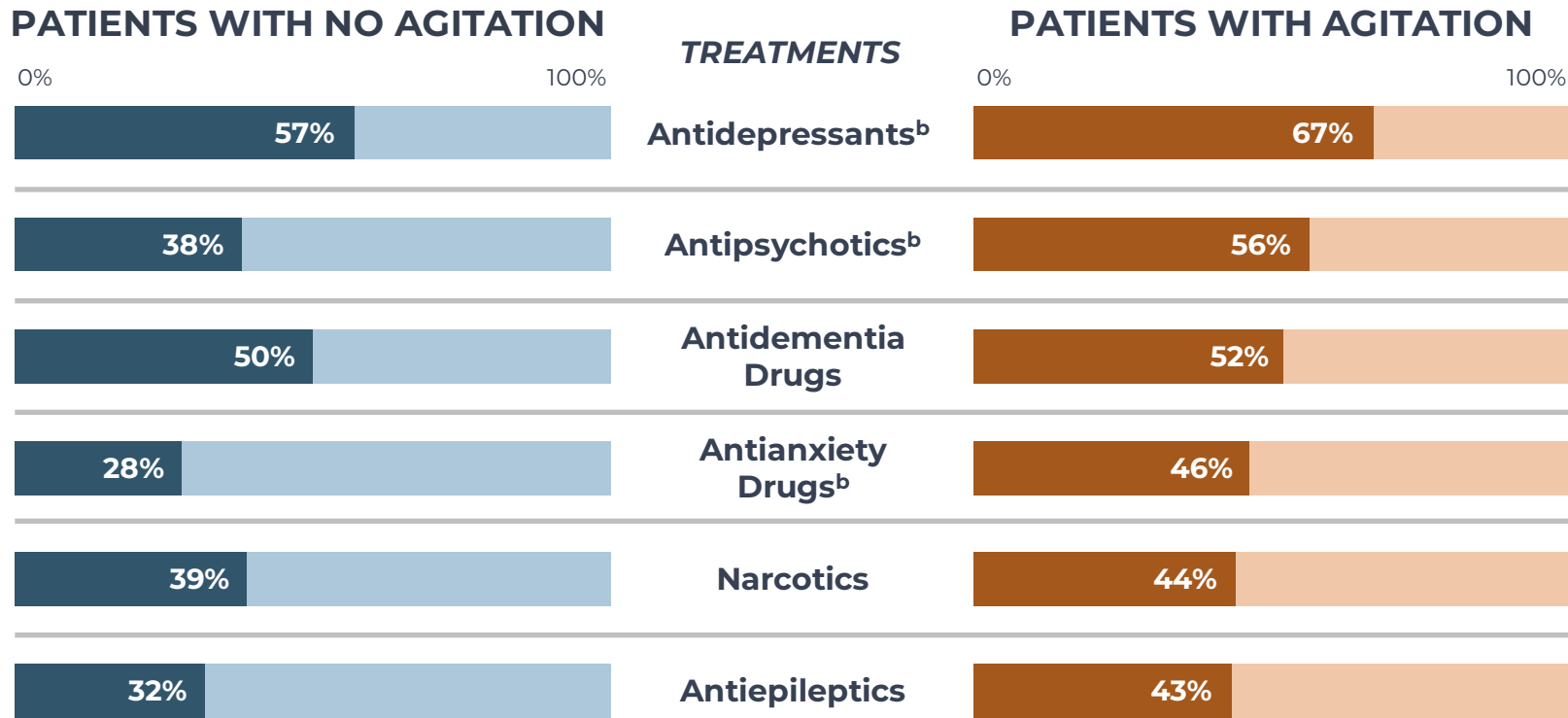
The most common forms of recorded resident-to-resident mistreatment include:



LTC, long-term care.

1. Lachs MS, et al. *Ann Intern Med.* 2016;165(4):229-236.

# AAD Is Associated with Higher Medication Use in LTC<sup>1,a</sup>



**POLYPHARMACY**

- Associated with a high incidence of adverse drug reactions and drug-drug interactions and may manifest as NPS in this elderly population<sup>1,2</sup>
- Known to increase the possibility of a “prescribing cascade,” in which side effects of drugs are misdiagnosed as symptoms of another medical condition resulting in further prescriptions and side effects<sup>2</sup>

<sup>a</sup>Compared to patients with dementia and no agitation.

<sup>b</sup>May require GDR<sup>3</sup>

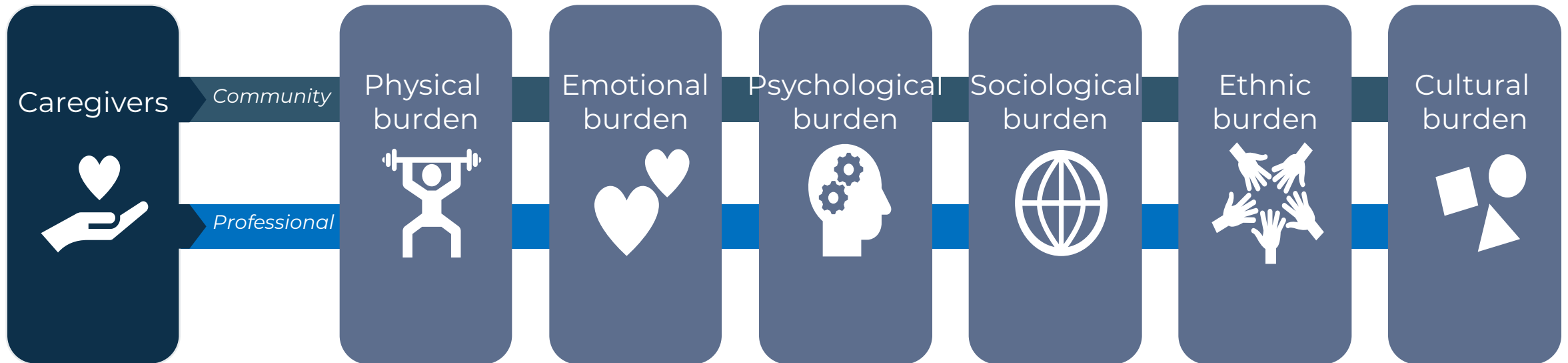
AAD, association associated Alzheimer’s dementia. LTC, long-term care. NPS, neuropsychiatric symptoms, GDR, gradual dose reduction.

1. Fillit H, et al. *Int J Geriatr Psychiatry*. 2021;36(12):1959-1969.

2. Aigbogun MS, et al. *BMC Neuro*. 2019;19(1):33.

3. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

# Many Professional Caregiving Themes Parallel Those of Family Caregiving, Including Burden of Patient Care<sup>1,2</sup>



1. McCarty EF and Drebing C. J Nurses Staff Dev. 2002;18(5):250-257.
2. Kunkle R, et al. West J Nurs Res. 2021;43(9):877-893.

# Agitation-associated Behaviors Have Been Associated With Substantial Burden to LTC Caregivers<sup>1-3</sup>

## Agitation-associated Behaviors<sup>3</sup>

Described as one of the most difficult, potentially dangerous, and emotionally distressing aspects of patient care

## Caregiver Burden<sup>4</sup>

Includes:

- Physical problems
- Emotional problems
- Loss of empathy/detachment
- Negative attitude toward job

## Caregiver Outcomes<sup>4</sup>

Expressed as:

- Physical fatigue and illness
- Emotional depletion
- Psychopathology
- Increased use of clinical services



**AAD could be considered a risk factor for caregiver burnout, reduced workability, and generally weaker health<sup>5</sup>**

AAD, agitation associated with Alzheimer's dementia. LTC, long-term care.

1. Kunkle R, et al. *West J Nurs Res.* 2021;43(9):877-893.

2. Fillit H, et al. *Int J Geriatr Psychiatry.* 2021;36(12):1959-1969.

3. Zeller A, et al. *Geriatr Nurs.* 2009;30(3):174-187.

4. McCarty EF and Drebing C. *J Nurses Staff Dev.* 2002;18(5):250-257.

5. Palm R, et al. *J Alzheimers Dis.* 2018;66(4):1463-1470.

# The LTC Industry Is Currently Facing a Serious Labor and Economic Crisis<sup>1,a</sup>



The ongoing struggle to find caregivers in this setting may affect quality of care for patients



CMS plans to propose a new federal staffing mandate to address current staffing challenges in nursing homes



**54%**

Are having to turn away prospective residents



**67%**

Are concerned their facility may have to close due to persistent workforce challenges



**78%**

Have hired temporary agency staff to adjust for staffing shortages



**84%**

Are facing moderate to high levels of staffing shortages<sup>b</sup>

<sup>a</sup>According to a recent AHCA survey of 524 NH providers.

<sup>b</sup>Defined as: "On one or more occasion, you could not fill all your shifts without agency or asking people to work overtime/extra shifts."

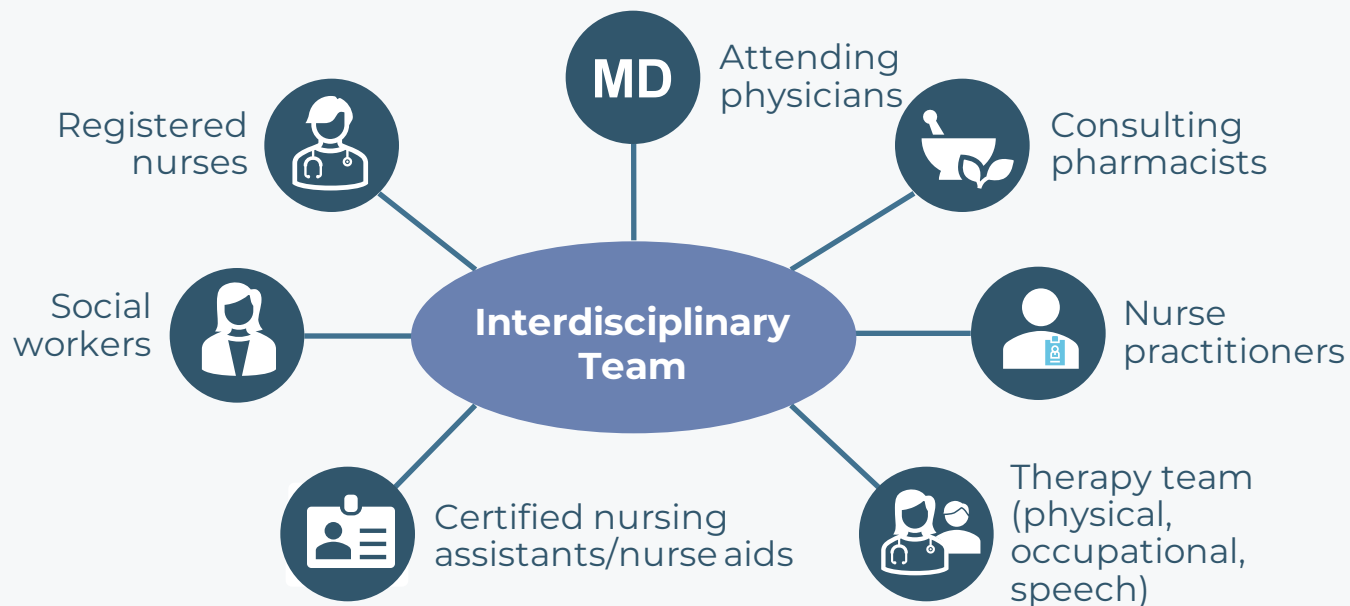
CMS, Center for Medicare & Medicaid Services. LTC, long-term care.

1. American Health Care Association. *State of the Nursing Home Industry: Survey of 524 Nursing Home Providers Highlights Persistent Staffing and Economic Crisis*. 2023. Available at: <https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF-Survey-December-2022.pdf>



# The Goal of the Interdisciplinary Team Is to Provide Patient-Centered Care<sup>1</sup>

The interdisciplinary team varies by setting and facility, but can be comprised of the following care providers<sup>2,3</sup>:



The interdisciplinary team assesses, coordinates, and manages comprehensive health care for each resident's varying needs<sup>4</sup>:



<sup>4</sup>In accordance with federal/state regulations (eg, 42 CFR 483.5, 42 CFR 483.10 through 483.75; CMS State Operations Manual Appendix PP)<sup>4,5</sup>  
 CMS, Center for Medicare & Medicaid Services. LTC, long-term care.

1. NEJM. NEJM Catalyst. "What Is Patient-Centered Care?" 2017. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559>.  
 2. Philip AM and Soper MH. Interdisciplinary Care Teams for Medicare-Medicaid Enrollees: Considerations for States. 2016. Available at: <https://www.chcs.org/resource/interdisciplinary-care-teams-for-medicare-medicicaid-enrollees-considerations-for-states/>

3. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

4. Stefanacci RG and Cusak CL. Ann Longterm Care. 2016;24(4):17-20.  
 5. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Committee on the Quality of Care in Nursing Homes. The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff. Washington (DC): National Academies Press (US); April 6, 2022.

# Economic Burden

Management of AAD in LTC residents is associated with significant healthcare resource utilization and costs<sup>1</sup>



~4 million persons receive care in ~15,000 nursing homes across the US each year<sup>2</sup>



Annual costs exceed

**\$168B**



Projected to grow to

**\$274B**  
by 2024

The **total incremental cost** of institutionalization associated with agitation<sup>3,a</sup>:



**\$4.3B**  
overall



**\$50,588**  
per individual

<sup>a</sup>According to a recent retrospective report, 2018 US dollars.  
B, billion. LTC, long-term care. US, United States.

1. Fillit H, et al. *Int J Geriatr Psychiatry*. 2021;36(12):1959-1969.
2. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Committee on the Quality of Care in Nursing Homes. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff*. Washington (DC): National Academies Press (US); 2022.
3. Cloutier M, et al. *Alzheimers Dement (NY)*. 2019;5:851-861.

# Treatment Considerations

A primary goal of developing a comprehensive, person-centered treatment plan is symptom relief<sup>1,2</sup>



## Differential diagnosis<sup>2,3</sup>

Careful evaluation for general medical, psychiatric, environmental, or psychosocial problems that may underlie the disturbance

- Assessment for the type, frequency, severity, pattern, and timing of symptoms



## Nonpharmacologic interventions<sup>2,3</sup>

If agitation does not cause significant danger or marked distress to the patient or others, symptoms are best treated with environmental or behavioral measures including:

- Behavioral management therapy or behavioral interventions
- Emotion-oriented approaches
- Stimulation-oriented treatments (e.g., recreational activity, art therapy, music therapy, and pet therapy)



## Pharmacologic interventions<sup>2,3</sup>

If nonpharmacologic measures are unsuccessful or symptoms are severe, dangerous, and/or cause significant distress, then judicious pharmacological intervention is recommended

- Antipsychotics are the pharmacological therapy recommended by the APA for agitation in dementia



**There is only one FDA-approved drug for treatment of AAD, and it is classified as an atypical antipsychotic<sup>4</sup>**

However, clinicians may prescribe other pharmacologic treatments, including<sup>3,5,6</sup>:

- ✓ Antipsychotics (typical and atypical)
- ✓ Anxiolytics or sedative-hypnotics
- ✓ Anticonvulsants
- ✓ Antidepressants
- ✓ Other medications

APA, American Psychiatric Association.

1. Kales HC, et al. *J Am Geriatr Soc.* 2014;62(4):762-769.

2. Reus IV, et al. *Am J Psychiatry.* 2016;173(5):543-546.

3. Rabins PV, et al. *Am J Psychiatry.* 2007;164(12 Suppl):5-56.

4. FDA. FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease. May 2023. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease>.

5. Aigbogun MS, et al. *BMC Neuro.* 2019;19(1):33.

6. Schneider LS, et al. *Am J Geriatr Psychiatry.* 2006;14(3):191-210.

# The Use of Antipsychotics in the LTC Setting Is Highly Regulated<sup>1</sup>

CMS' regulatory oversight for psychotropic medications<sup>a</sup> ensures proper use<sup>2</sup>

## Requirements for proper use:

Psychotropics<sup>a</sup> cannot be prescribed without a documented diagnosis, and certain drug classes have additional regulations<sup>2</sup>



## Additional monitoring requirements:

If psychotropics are prescribed, behavioral symptoms must be reviewed at least quarterly to determine if the dose can be reduced or discontinued (i.e., GDR)<sup>2</sup>



## Auditing for inaccurate coding:

CMS will audit LTC facilities' MDS documentation and assessment of schizophrenia due to historical erroneous diagnoses and concern for residents being prescribed unnecessary antipsychotics<sup>3</sup>



## Consequences of inaccurate coding:

CMS will downgrade quality measure ratings in cases of inaccurate coding (e.g., lacking comprehensive psychiatric evaluations or noting behaviors related to dementia versus schizophrenia)<sup>3</sup>



<sup>a</sup>Includes antipsychotic, antidepressant, antianxiety, and hypnotic drugs.

CMS, Center for Medicare & Medicaid Services. GDR, gradual dose reduction. LTC, long-term care. MDS, minimum data set.

1. Assistant Secretary for Planning and Evaluation. Antipsychotic Medication Prescribing in Long-Term Care Facilities Increased in the Early Months of the COVID-19 Pandemic. 2022. Available at: <https://aspe.hhs.gov/reports/antipsychotic-use-ltcfs-early-months-covid-19-pandemic#:~:text=Prescriptions%20dispensed%20for%20antipsychotics%20in,to%2020.5%20thousand%20in%202019.>
2. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

3. Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute. Centers for Medicare & Medicaid Services (CMS). QSO-23-05-NH, 1-18-23. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/updates-nursing-home-care-compare-website-and-five-star-quality-rating-system-adjusting-quality>

# Inappropriate Use of Psychotropic Drugs in LTC Settings

There has long been concern about inappropriate use of psychotropic drugs, namely antipsychotics, in LTC residents<sup>1</sup>



A 1986 investigation into quality of care in nursing homes found that psychotropic drugs were being used inappropriately to sedate patients to keep behavioral- and workforce-related issues at bay<sup>1</sup>



In 2006, the Psychosocial Outcome Severity Guide implemented strategies to reduce inappropriate use of psychotropic drugs<sup>2</sup>



In 2012, CMS amplified monitoring use of psychotropic drugs in nursing home residents through targeted quality measures for both short- and long-term stays<sup>2</sup>



CMS continues to monitor psychotropic drug use in nursing home residents, with a focus on appropriate utilization<sup>2</sup>

CMS, Center for Medicare and Medicaid Services. NH, nursing home. OBRA, Omnibus Budget Reconciliation Act. US, United States.

1. Hughes C and Lapane K. *Drugs Aging*. 2005;22(4):339-351.

2. US Department of Health and Human Services; Office of Inspector General Christi A. Grimm. Long-Term Trends of Psychotropic Drug Use in Nursing Homes. Nov. 2022.

# CMS Maintains Focus on Regulating Inappropriate Antipsychotic Use

Challenges associated with antipsychotic use in LTC facilities can include<sup>1,2</sup>:



Questions over on-label use counting against facilities' overall antipsychotic measures<sup>3,4</sup>



Ambiguity around family involvement in antipsychotic decision-making for patients with dementia<sup>1</sup>



Risk of negative impact on regulatory and quality measures associated with antipsychotic use<sup>5</sup>



High burden of documentation to support appropriate utilization, including GDR<sup>6</sup>

**There is a need for increased guidance surrounding appropriate antipsychotic use in LTC facilities<sup>7</sup>**

CMS, Center for Medicare and Medicaid Services. GDR, gradual dose reduction.

1. Tija J, et al. *J Am Geriatr Soc*. 2017;65(1):59-65.
2. Farshaw S, et al. *J Am Med Dir Assoc*. 2020;21(2):233-239.
3. HHS Office of the Inspector General. CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes. May 2021. Available at: <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.asp>.

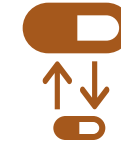
4. AMA. Appropriate Use of Antipsychotic Medications in Nursing Homes. Available at: <https://www.ama-assn.org/system/files/a22-703.pdf>.
5. Update Report on the National Partnership to Improve Dementia Care in Nursing Homes. CMS. June 2016. Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-16-28-Partnership-Update-Report.pdf>.
6. Ghairatmal M, et al. *Am J Geriatr Psychiatry*. 2020;28:4S.
7. Hughes C, Lapane K. *Drugs Aging*. 2005;22(4):339-351.

# Specific Situations May Require Consideration of Antipsychotic Medication

**Patient-centered care, including a complete assessment and nonpharmacologic strategies, should be attempted prior to initiating pharmacologic therapy with antipsychotic medication<sup>1</sup>**



Dangerous/distressing symptoms were **not relieved** with multiple nonpharmacological approaches (if not clinically contraindicated)



Dangerous/distressing symptoms **returned** after GDR attempt



Symptoms are significantly **distressing** to the resident



Behavioral symptoms present a **danger** to resident or others

## Examples of groups focused on reducing inappropriate antipsychotic use:



**DRIVE TO DEPRESCRIBE**  
Optimizing Medication Use in PALTC

With resources from AMDA to help **optimize medication use** in LTC facilities<sup>2</sup>



ASCP provides a system of checks and balances to **improve antipsychotic oversight**<sup>3</sup>

AMDA, American Medical Directors Association. ASCP, American Society of Consultant Pharmacists. GDR, gradual dose reduction. LTC, long-term care. PALTC, Post-Acute and Long-Term Care Medicine.

1. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care, Centers for Medicare & Medicaid Services (CMS), Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

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# Summary



AAD is highly prevalent and present in all stages and severities of Alzheimer's dementia<sup>1</sup>



AAD is associated with Tau pathology and increased norepinephrine, serotonin deficits, and dopamine dysregulation<sup>2-7</sup>



AAD is associated with substantial patient and caregiver burden and long-term consequences as well as significant healthcare resource utilization and costs<sup>8,9</sup>



Antipsychotic use is highly regulated by CMS in an effort to curb inappropriate use and ensure appropriate use, including use in specific situations where antipsychotic medications may be indicated<sup>10,11</sup>



There is only one FDA-approved drug for treatment of AAD, and it is classified as an atypical antipsychotic.<sup>12</sup> However, clinicians may prescribe other unapproved medications<sup>13-15</sup>

AAD, agitation associated with Alzheimer's dementia. CMS, Center for Medicare and Medicaid Services. FDA, US Food and Drug Administration. LTC, long-term care.

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11. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

12. FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease. May 2023. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease>.

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# The Interdisciplinary Team is Important For Ensuring Appropriate Use of Antipsychotics in the LTC Setting<sup>1</sup>



**The Interdisciplinary Team**  
must address any triggers of distress, including:



**Psychological**



**Medical**



**Physical**



**Environmental**



## **CMS.gov**

- Tracks use of antipsychotics in nursing homes
- Seeks to discourage overutilization of psychotropic medications in nursing homes<sup>1,2</sup>



## **Documentation**

- Nonpharmacological approaches must be documented first
- Indication for antipsychotic prescriptions must be well-documented



## **Limited Antipsychotic Use**

- Given only when necessary to treat a specific diagnosed and documented condition
- Received in conjunction with GDR and other non-pharmacologic interventions
- As needed orders limited to 14 days

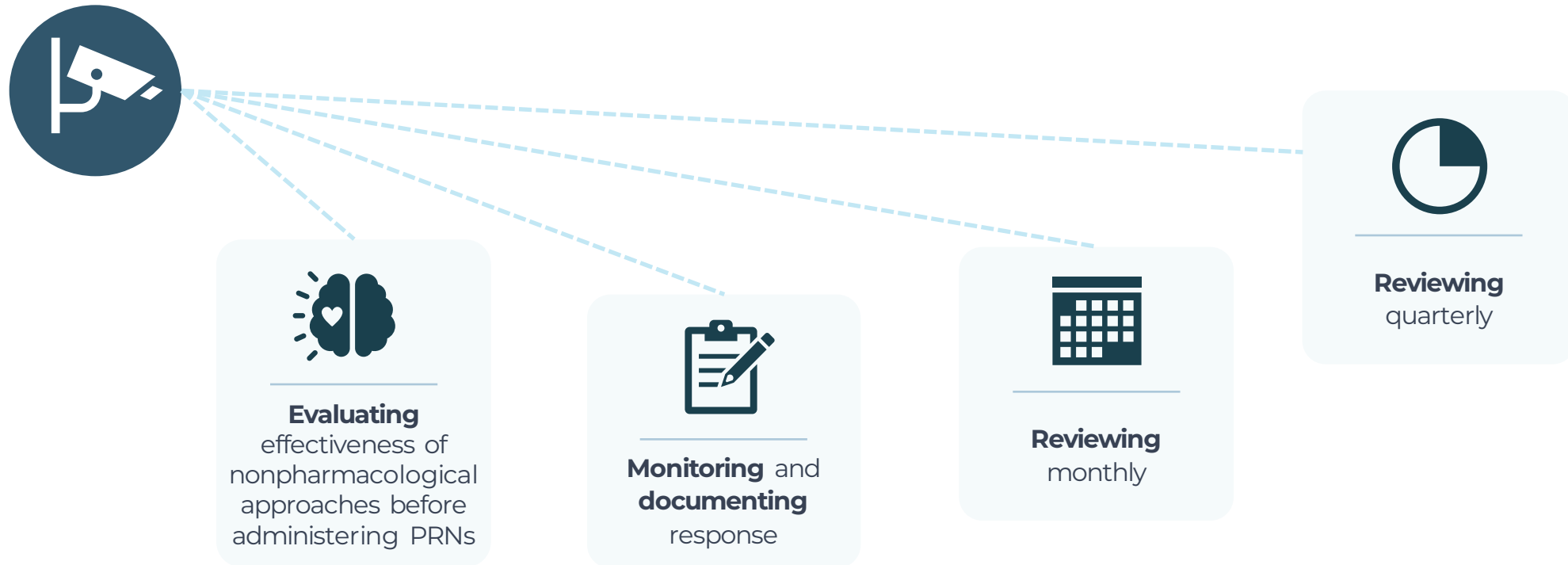
CMS, Center for Medicare & Medicaid Services. GDR, gradual dose reduction. LTC, long-term care.

1. Assistant Secretary for Planning and Evaluation. Antipsychotic Medication Prescribing in Long-Term Care Facilities Increased in the Early Months of the COVID-19 Pandemic. 2022. Available at: <https://aspe.hhs.gov/reports/antipsychotic-use-ltcfs-early-months-covid-19-pandemic#:~:text=Prescriptions%20dispensed%20for%20antipsychotics%20in,to%2020.5%20thousand%20in%202019.>

2. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

# Medications Are Subject to Regular Monitoring for Each Resident<sup>1</sup>

Required medication monitoring specified by CMS includes:

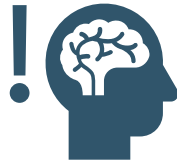


CMS, Center for Medicare & Medicaid Services. LTC, long-term care. PRN, as-needed.

1. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.

# Certain Circumstances Warrant Evaluation of a Resident and Medication(s), Although the Content And Extent of the Evaluation May Vary With the Situation<sup>1</sup>

The evaluation process is important when selecting initial medications and/or nonpharmacological approaches and when deciding whether to modify or discontinue a current medication



- New, persistent, or recurrent clinically significant symptom or problem
- Worsening of an existing problem or condition
- Clinically significant change in condition/status
- Admission or re-admission



- Orders for PRN antipsychotics which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and APs



- Irregularity identified in the pharmacist's medication regimen review
- New medication order or renewal of orders

LTC, long-term care. PRN, as-needed.

1. State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care. Centers for Medicare & Medicaid Services (CMS). Rev. 211. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>.