Review of Care and Services for a Resident with Dementia
Changes to the SOM at F309 and F329
Omnicare
Pharmacy Services
July 2013

F309 – §483.25 Quality of Care
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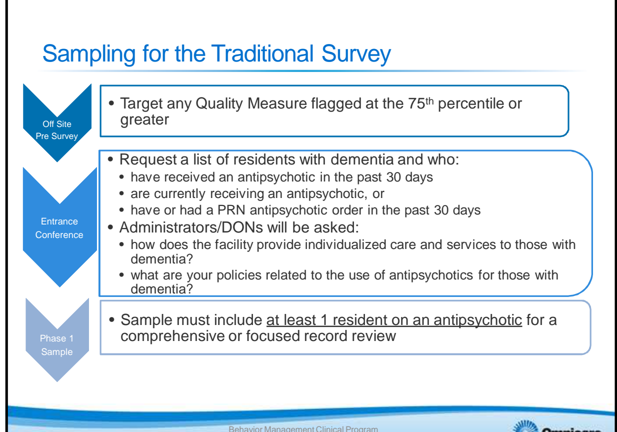
Sampling for the Traditional Survey
Off Site Pre Survey
• Target any Quality Measure flagged at the 75th percentile or greater
Entrance Conference
• Request a list of residents with dementia and who:
• have received an antipsychotic in the past 30 days
• are currently receiving an antipsychotic, or
• have or had a PRN antipsychotic order in the past 30 days
• Administrators/DONs will be asked:
• how does the facility provide individualized care and services to those with dementia?
• what are your policies related to the use of antipsychotics for those with dementia?
Phase 1 Sample
• Sample must include at least 1 resident on an antipsychotic for a comprehensive or focused record review
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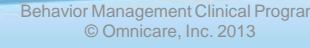
F309 - **New Section**
"Review of Care and Services for a Resident with Dementia"

- Begins by stating: "Use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs."
- Keys to Recognition and Management
  - Individualized interventions (including direct care and activities)
  - Person-Centered or Person-Appropriate Care
    - *"Activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed and medical treatment should be tailored to an individual's risk factors, current conditions, past history, and details of any present symptoms."*
  - Proper description of Behavioral or Psychological Symptoms of Dementia (BPSD)

Overview of Dementia and Behavioral Health

- What is dementia?
  - *Dementia is not a specific disease. It is a descriptive term for a collection of symptoms that can be caused by a number of disorders that affect the brain.*
  - *Some individuals with dementia may have coexisting symptoms or psychiatric conditions such as depression or bipolar affective disorder, paranoia, delusions or hallucinations. Progressive dementia may exacerbate these and other symptoms.*
- What is a behavior?
  - *Human behavior is the response of an individual to a wide variety of factors.*
  - *Behavior often represents a person's attempt to communicate an unmet need, discomfort or thoughts that they can no longer articulate.*
  - *Because behavioral symptoms may be caused by medical conditions such as delirium, medication side effects, and psychiatric symptoms such as delusions or hallucinations, these should be considered as possible causes in addition to environmental triggers.*



Cause of Dementia or Dementia-like Symptoms

Types of Dementia

- Alzheimer's disease
- Vascular dementia
- Lewy body dementia
- Fronto-temporal dementia
- Huntington's disease
- Creutzfeldt-Jakob disease

Other Causes of Dementia Symptoms

- Medication reactions/side effects
- Metabolic problems and endocrine abnormalities
- Nutritional deficiencies
- Infections
- Poisoning
- Brain tumors
- Anoxia or hypoxia
- Heart problems
- Lung problems

"Although it is common in very elderly individuals, dementia is not a normal part of the aging process."

Delirium

- "*An acute confusional state that includes symptoms very similar to those of dementia and psychiatric disorders. The diagnostic criteria for delirium include a fluctuating course throughout the day, inattention as evidenced by being easily distracted, cognitive changes, and perceptual disturbances*"
- Often characterized as hyperactive (e.g., extreme restlessness, climbing out of bed), but more commonly delirium is hypoactive often leading to the misdiagnosis of dementia or a psychiatric disorder.
- Delirium is particularly common post-hospitalization and with infections
- Delirium increases the risk of developing dementia and individuals with dementia are at greater risk of developing delirium
- Failure to recognize and act quickly may result in poor health outcomes, hospitalization or death

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Therapeutic Interventions or Approaches

- Caregivers and practitioners are expected to:
  - understand or explain the rationale for interventions/approaches
  - monitor the effectiveness of those interventions/approaches
  - provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences.
- Identifying the frequency, intensity, duration and impact of behaviors, as well as the location, surroundings or situation in which they occur may help staff and practitioners identify individualized interventions or approaches to prevent or address the behaviors…. In many situations, medications may not be necessary; staff/practitioners should not automatically assume that medications are an appropriate treatment without a systematic evaluation of the resident.
- Examples of suggested ideas to prevent BPSD include (but are not limited to):
  - Arranging staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment);
  - Identifying and applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care;
  - Understanding that the resident may be responding predictably given the situation or surroundings (e.g., being awakened at night in his/her bedroom by unfamiliar staff); and
  - Matching activities for a resident with dementia to his/her individual cognitive and other abilities and the specific behaviors in that individual based on the assessment.

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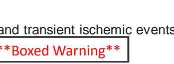
Medication Use in Dementia (From F309)

- "*It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address [BPSD] without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors.*"
- Common complications of antipsychotics:
  - Movement disorders
  - Falls
  - Hip Fractures
  - Cerebrovascular accidents and transient ischemic events
  - Increased risk of death **Boxed Warning**



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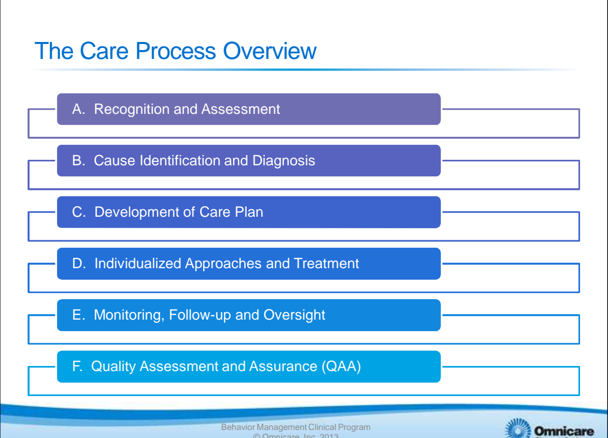
Resident and/or Family/Representative Involvement

- *"CMS expects that the resident and family/representatives, to the extent possible, are involved in helping staff to understand the potential underlying causes of behavioral distress and to participate in the development and implementation of the resident's care plan."*
- How have you involved them in discussions about:
  - Potential approaches to address behaviors?
  - Potential risks and benefits of psychopharmacological medications (including boxed warnings)?
  - Expected duration of use of a medication?
  - Use of individualized approaches?
  - Plans to evaluate the effects of treatment?
  - Pertinent alternatives?
  - Necessity of informed consent (**only applicable in some states**)

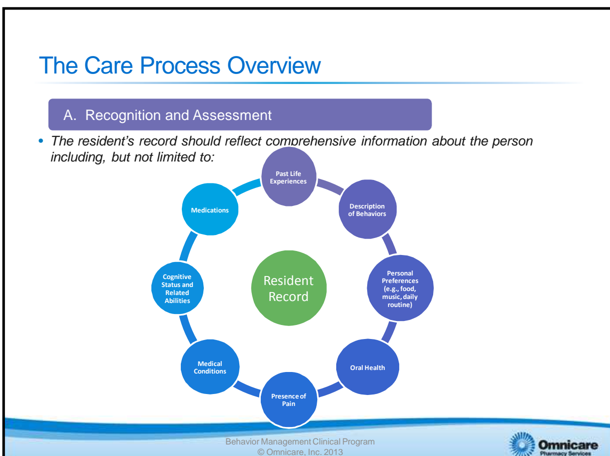
The Care Process Overview



The Care Process Overview

A. Recognition and Assessment

- *The resident's record should reflect comprehensive information about the person including, but not limited to:*



The Care Process Overview

A. Recognition and Assessment

- How do they communicate pain? Discomfort? Hunger? Thirst? Frustration? Boredom? Anxiety? Fatigue?
- *"…staff should specifically describe the behavior (including potential underlying causes, onset, duration, intensity, precipitating events or environmental triggers, etc.) and related factors (such as appearance and alertness) in the medical record with enough detail of the actual situation to permit cause identification and individualized interventions"*
  - "Describing the details and possible consequences of resident behaviors helps to distinguish expressions such as restlessness or continual verbalization from potentially harmful actions such as kicking, biting or striking out at others. This description alone does not suggest that a specific intervention is or is not indicated;"
  - *"Noting that the resident is generally "violent," "agitated" or "aggressive" does* ***not*** *identify the specific behavior exhibited by the resident. Noting instead that the resident responds in crowded, busy group activities by yelling or throwing furniture reflects not only a potential safety issue but should result in the resident being provided alternative activities to meet his/her needs."*

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The Care Process Overview

B. Cause Identification and Diagnosis

- Identify possible risk and casual/contributing factors for behaviors:
  - Co-existing medical or psychiatric conditions (e.g., pain, constipation, etc.)
    - Uncontrolled pain is known to cause or contribute to changes in mood/behavior
  - Adverse drug effects (e.g., anticholinergic side effects)
  - Significant changes in physical, mental, or psychosocial status → ***"must immediately consult with the resident's physician"***
    - *If two or more areas of decline or improvement are noted, a Significant Change in Clinical Status Assessment (SCSA) should be considered*

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The Care Process Overview

B. Cause Identification and Diagnosis

- If medical causes are ruled out, consider:
  - *Boredom; lack of meaningful activity or stimulation during customary routines and activities;*
  - *Anxiety related to changes in routines such as shift changes, unfamiliar or different caregivers, change of (or relationship with) roommate, inability to communicate;*
  - *Care routines (such as bathing) that are inconsistent with a person's preferences;*
  - *Personal needs not being met appropriately or sufficiently (e.g., hunger, thirst, bowels);*
  - *Fatigue/Disturbance in sleep pattern*
  - *Environmental factors (e.g., noise could lead to discomfort or delusions)*
  - *Mismatch between the activities or routines selected and the resident's cognitive and other abilities to participate in those activities/routines.*

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The Care Process Overview

C. Development of Care Plan

- Each individual care plan must:
  - Be specific to the resident
  - Involve the resident and family/representative
- The care plan should include:
  - Common behavioral expressions and expected responses to interventions
    - *"Certain behavior may be anticipated and sometimes may be preventable based on understanding the underlying causes and possible triggers for each individual."*
  - Goals for monitoring of all interventions
  - Any medications - *"In certain cases, residents may benefit from the use of medications."*

Care Planning for Medications Must Include:		
Indication/rationale for use	Specific target behaviors and expected outcomes	Dosage
Duration	Monitoring for efficacy and/or adverse consequences	Plans for gradual dosage reduction (GDR) when applicable

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The Care Process Overview

C. Development of Care Plan

- Questions to ask if a psychopharmacological medication is initiated or continued:
  - What was the person trying to communicate through their behavior?
  - What were the possible reasons for the person's behavior that led to the initiation of the medication?
  - What other approaches and interventions were attempted prior to the use of the antipsychotic medication?
  - Was the family or representative contacted prior to initiating the medication?
  - Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record?
  - Was the medication adjusted to the lowest possible dosage to achieve the desired therapeutic effects?
  - Were gradual dose reductions planned and behavioral interventions, unless clinically contraindicated, provided in an effort to discontinue the medication?
  - Was the interdisciplinary team, including the primary care practitioner, involved in the care planning process?
  - How does the staff monitor for the effectiveness and possible adverse consequences of the medication?

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The Care Process Overview

D. Individualized Approaches and Treatment

- Identify and document specific target behaviors, expressions of distress and desired outcomes
- Implement appropriate, individualized, person-centered interventions and document the results
- Communicate and consistently implement the care plan, over time and across various shifts
- Staffing and Staff Training

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The Care Process Overview

D. Individualized Approaches and Treatment

Staffing

- There must be "sufficient numbers of staff to consistently implement the care plan"
  - Quantity (direct care and supervisory)
  - Quality (to meet the needs of the resident's assessments and care plan)
- "Strive to staff in a way that optimizes familiarity with residents"
- Assess for "caregiver stress"

Staff Training

- Must "demonstrate competency in skills and techniques necessary to care for the resident's needs as identified through resident assessments, and as described in the plan of care"
- Nursing Assistants must have:
  - Performance review (at least every 12 months)
  - Regular in-service education based on the outcome of the reviews
  - Training in care of individuals with dementia and related behaviors (initially after being hired and annually)

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E. Monitoring, Follow-up and Oversight

- The interdisciplinary team (IDT) should:
  - review a resident's progress toward defined goals,
  - adjust interventions as needed
  - Identify when care objectives are met
- When "concerns are identified related to effectiveness or potential or actual adverse consequences of a resident's medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident's care"

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The Care Process Overview

F. Quality Assessment and Assurance (QAA)

- *"The medical director and the quality assessment and assurance committee can help the facility evaluate existing strategies for coordinating the care of a resident with dementia and ensure that facility policies and procedures are consistent with current standards of practice."*
- *The QAA oversight should include:*
  - resident care policies and how they are monitored for implementation
  - Staff training (including nursing, dietary, therapy or rehabilitation staff, social workers) on how to communicate with and address behaviors in residents with dementia
  - Ensuring "sufficient staff to implement the care plan for residents with dementia, so that medication is not used instead of pertinent non-pharmacological interventions, unless clinically contraindicated"
  - Analysis of data collected to monitor the pharmacological and non-pharmacological interventions used
  - Monitoring responses to the issues and concerns identified through the consultant pharmacist medication regimen review

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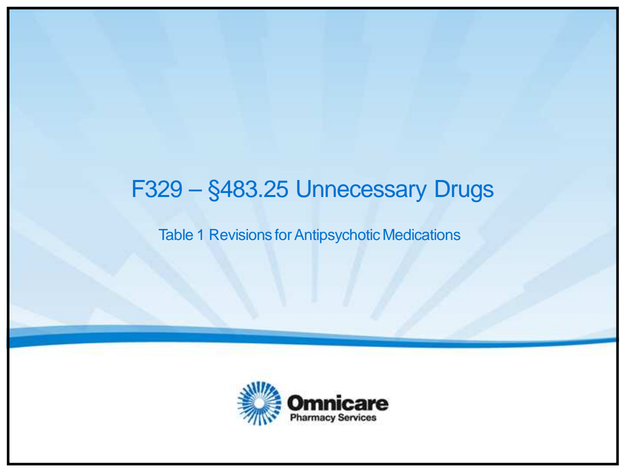
F329 – §483.25 Unnecessary Drugs
Table 1 Revisions for Antipsychotic Medications
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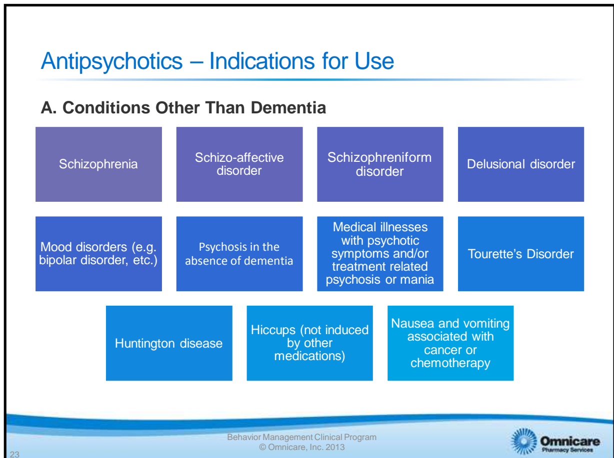
Antipsychotics – Indications for Use
A. Conditions Other Than Dementia
Schizophrenia
Schizo-affective disorder
Schizophreniform disorder
Delusional disorder
Mood disorders (e.g. bipolar disorder, etc.)
Psychosis in the absence of dementia
Medical illnesses with psychotic symptoms and/or treatment related psychosis or mania
Tourette's Disorder
Huntington disease
Hiccups (not induced by other medications)
Nausea and vomiting associated with cancer or chemotherapy
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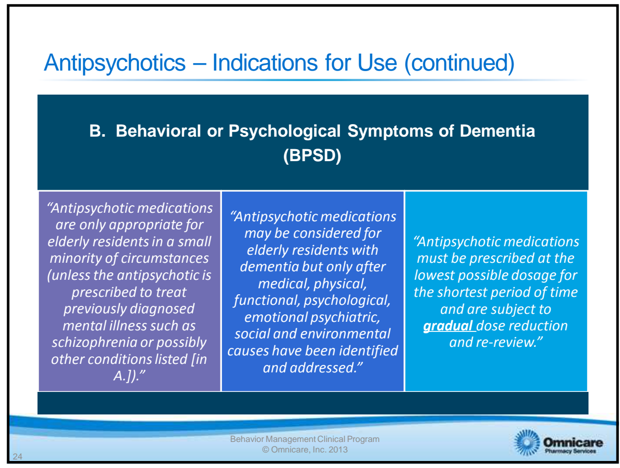
Antipsychotics – Indications for Use (continued)
B. Behavioral or Psychological Symptoms of Dementia (BPSD)
"Antipsychotic medications are only appropriate for elderly residents in a small minority of circumstances (unless the antipsychotic is prescribed to treat previously diagnosed mental illness such as schizophrenia or possibly other conditions listed [in A.])."
"Antipsychotic medications may be considered for elderly residents with dementia but only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed."
"Antipsychotic medications must be prescribed at the lowest possible dosage for the shortest period of time and are subject to gradual dose reduction and re-review."
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Inadequate Indications for Antipsychotic Use

Wandering	*Poor self-care*	*Restlessness*
Impaired memory	*Mild anxiety*	*Insomnia*
Inattention or indifference to surroundings	*Sadness or crying alone that is not related to depression or other psychiatric disorders*	*Uncooperativeness (e.g. refusal of or difficulty receiving care)*
Fidgeting	*Nervousness*	

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Criteria for Use of An Antipsychotic

- *"All of the [preceding] highlight conditions/diagnoses where antipsychotic medications may possibly be appropriate, but diagnoses alone do not warrant the use of an antipsychotic unless the following criteria are also met:"*
  - ***The behavioral symptoms present a danger to the resident or others***

  AND *one or both of the following:*
  - *The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity);*

  OR
  - *Behavioral interventions have been attempted and included in the plan of care, except in an emergency.*
- *Acute Situations/Emergency*
  1) *Use must be limited to 7 days or less*
  2) *A clinician with the IDT must evaluate and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication."*
  3) *If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following the resolution of the acute psychiatric event.*

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Criteria for Use of An Antipsychotic (continued)

Enduring Conditions (i.e., non-acute; chronic or prolonged condition)

- "Before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior/s must be clearly and specifically identified and documented."
- Monitoring must ensure that ALL 4 of the following are TRUE about the behavioral symptom:
  1) Not due to a medical condition or problem (e.g., pain, medication side effect, etc.) that would improve or resolve if treated/the offending medication(s) are discontinued;
  2) Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response)
  3) Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed;
  4) Persistent – as documented in the medical record, the situation or condition continues or recurs over time (persists) and that other approaches that have been attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected by the behaviors/symptoms as described above

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Beyond CMS – An Industry-wide Consensus

- The American Geriatrics Society (AGS)
  - "Medication treatment of behavioral disturbances of dementia is of limited efficacy and should be used only after environmental and nonpharmacologic techniques have been implemented"
  - "No psychoactive medication prescribed to treat neuropsychiatric symptoms of dementia should be continued indefinitely, and attempt at drug withdrawal should be made regularly (e.g., every 3-6 months)"
  - "The goal (of treatment) is reduction, rather than elimination, of the distressing behavior…"
- The American Medical Directors Association (AMDA)
  - "The use of antipsychotic medications should be limited to treating dementia-related behaviors that are unresponsive to conservative management and done only after thoughtful evaluation, identification of appropriate indications, and considerations of the benefits and risks involved."
  - "The goal of using antipsychotic medications, as with any psychopharmacological medications, is to address behavioral or mood symptoms and/or their underlying causes while preserving or enhancing function and quality of life. If the medication causes excessive or unwanted sedation or impairs function and diminishes quality of life, then its use may not be appropriate and should be reconsidered."
  - "Prescribing an antipsychotic medication, except in an emergency, should be done only after an attempt to determine if there are other environmental or medical factors causing these types of symptoms, and after taking appropriate actions when other causes are suspected (e.g., treating a urinary tract infection or providing medication for arthritis pain)."

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New Admissions (**New Section of F329**)

- For residents who do not require PASRR [Pre-Admission Screening and Resident Review] and are admitted on an antipsychotic, the facility MUST re-evaluate the use of the antipsychotic medication at the time of admission and/or within 2 weeks of admission (at the time of the initial MDS assessment) AND consider whether or not the medication can be reduced (tapered) or discontinued.

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Daily Dose Thresholds for Antipsychotics Used for BPSD

Generic Name	Maximum Total Dosage per day	Generic Name	Maximum Total Dosage per day
First Generation or Typical Agents		**Second Generation or Atypical Agents**	
chlorpromazine (Thorazine)	75 mg	aripiprazole (Abilify)	10 mg
fluphenazine (Prolixin)	4 mg	clozapine (Clozaril)	50 mg
haloperidol (Haldol)	2 mg	olanzapine (Zyprexa)	5 mg (previously 7.5 mg)
loxapine (Loxitane)	10 mg	quetiapine (Seroquel)	150 mg
molindone (Moban)	10 mg	risperidone (Risperdal)	2 mg
perphenazine (Trilafon)	8 mg	ziprasidone (Geodon)	**
thioridazine (Mellaril)	75 mg	paliperidone (Invega)	**
thiothixene (Navane)	7 mg	asenapine (Saphris)	**
trifluoperazine (Stelazine)	8 mg	iloperidone (Fanapt)	**
		lurasidone (Latuda)	**

Higher doses warrant closer review for adverse effects and risk/benefit evaluation.
* = Due to additional boxed warnings of QTc prolongation, its use should be avoided
** = no studies have been conducted or have results available to assess the drug's safety or efficacy in older adults with dementia.

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Monitoring and Effectiveness

- *Monitor for:*
  - *ongoing effectiveness*
  - *potential adverse consequences*
- *Evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines) being given to the resident.*
- *Surveyors should investigate further in cases where:*
  - *more than one antipsychotic agent has been prescribed, OR*
  - *where an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added.*
- *After initiating or increasing the dose of an antipsychotic, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, but often more frequently, depending on the resident's response to the medication) to determine:*
  - *the effectiveness of the antipsychotic AND*
  - *the potential for reducing or discontinuing the dose based on target symptoms AND*
  - *any adverse effects or functional impairment.*

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Potential Adverse Consequences of Antipsychotics

Category	Specific Adverse Consequences
General	Anticholinergic Effects (see Table II), falls, excessive sedation
Cardiovascular	Cardiac arrhythmias, orthostatic hypotension
Metabolic	↑ total cholesterol, ↑ triglycerides, unstable or poorly controlled blood sugar, weight gain
Neurologic	Akathisia, parkinsonism, tardive dyskinesia, neuroleptic malignant syndrome, stroke, transient ischemic attack

"If the antipsychotic medication is identified as probably causing or contributing to adverse consequences as identified above, the facility must act upon this. In some cases, the benefits of treatment will still be considered to outweigh the risks or burdens of treatment, so the medication may be continued; however, the facility and prescriber must document the rationale for the decision and also that the resident, family member or legal representative is aware of and involved in the decision to continue the medication."

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