Project PAUSE: Effective Solutions for Improving Clinical Care in Long-Term Care Settings

PROJECT pause

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Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) is a coalition of national patient and professional organizations collectively advocating on clinical care regulatory and legislative issues in long-term care (LTC) and the community. Project PAUSE aims to educate policymakers and the public about clinical care issues in long-term care and the community and collectively advocate for effective solutions. Members of Project PAUSE include patient and family caregiver organizations, long-term care groups, primary care associations, geriatric and mental health specialty provider associations, Alzheimer's disease and other dementia organizations, and mental health organizations. Project PAUSE consistently engages with the Centers for Medicare & Medicaid Services (CMS) and congressional leaders to promote policies in LTC settings that will curb the inappropriate use of antipsychotics and ensure access and appropriate use of these medications by patients who need them.

Project PAUSE is convened by the Alliance for Aging Research and the American Society of Consultant Pharmacists.

To learn more about Project PAUSE, please visit our website.

Executive Summary

The Centers for Medicare and Medicaid Services (CMS) document and report antipsychotic utilization rates in long-term care settings throughout the country. In March 2012, CMS launched a quality initiative with the goal of decreasing use of antipsychotics in nursing homes by 15% by the end of 2012.[1] This initiative established the current antipsychotic utilization rate quality measure and created *The National Partnership to Improve Dementia Care* (National Partnership).

The National Partnership's official measure to determine antipsychotic utilization rates is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome and the percentage of short-stay nursing home residents who are initiated on an antipsychotic after admission to the skilled nursing facility (SNF) (see figure 1). The National Partnership adopted these three excluded conditions as they have been recognized under CMS regulations since 2006, but it is important to note that these conditions are not the only U.S. Food and Drug Administration (FDA) approved indications for antipsychotic medication use.[2,3] Project PAUSE has complied a full list of FDA-approved adult indications for first-generation antipsychotics (see figure 2) and second-generation antipsychotics (see figure 3).[4]

The current measure utilized to determine CMS antipsychotic quality measures uses the medication list from the minimum data set (MDS), excluding any residents diagnosed with schizophrenia, Huntington's chorea, and/or Tourette's syndrome. This current measure does not take advantage of the interdisciplinary use of the Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual (see figure 4). The RAI is used by nursing homes and long-term care facilities (LTCFs) to gather information on a resident's clinical needs and it allows care teams to ojectively document care plans. This documentation can be used to identify resident strengths and needs and helps guide clinical interventions and reinforce best practices. This RAI resource utilizes clinical rationale to determine whether or not a patient requires a gradual dose reduction (GDR) of an antipsychotic medication or whether or not an antipsychotic mediation is clinically contraindicated.

In order for CMS to enforce best clinical practices and ensure appropriate antipsychotic utilization in nursing homes and LTCFs, the agency should incorporate a meaningful antipsychotic utilization measure using these inputs outlined in CMS' RAI manual. To assist the National Partnership and CMS in enforcing the antipsychotic utilization measures outlined in the RAI, Project PAUSE proposes that the agency update the quality measure to reflect only those residents using inappropriate antipsychotic drugs as determined by their prescriber and consultant pharmacist and verified on the RAI.

In addition to this critical improvement of the National Partnership's quality measure, Project PAUSE also seeks to help identify opportunities for integration of diagnostic

criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings in order to improve provider and surveyor knowledge gaps in the diagnosis and management of neuropsychiatric symptoms (NPS). Lastly, Project PAUSE encourages federal collaboration to recognize all current FDA-approved uses for psychotropic and antipsychotic medications for the treatment of NPS.

A summary list of our recommendations include:

1. Removing the requirement to count residents in SNFs who are appropriately prescribed antipsychotics for FDA-approved indications, from quality metrics for both short- and long-term stay residents receiving standing or as needed (PRN) antipsychotics medications.
2. Expanding CMS recognition of FDA-approved uses for psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late-life.
3. Integrating diagnostic criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings.
4. Sponsorship of population health studies which result in evidence-based clinical guidelines guiding the use of psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late-life.
5. Legislative action to establish additional opportunities for training of long-term care nursing and clinical staff.

Background on Neuropsychiatric Symptoms (NPS) of Dementia

While cognitive impairment is regarded as the hallmark indicator of dementia, neuropsychiatric symptoms (NPS) are nearly as universal, with one or more symptoms affecting nearly all people with dementia over the illness course. NPS may include wandering, sleep issues, agitation, depression, lack of emotion (apathy), aggression, and psychosis, and evidence finds such symptoms often result in greater impairment in activities of daily living, poorer quality of life, more rapid disease progression, greater morbidity, an increase in direct cost of care, and earlier institutionalization.[5-10] These symptoms also result in increased caregiver burden due to the emotional, financial, and physical difficulties associated with caring for the persons exhibiting them.[11] NPS can also pose a risk to other residents and staff members in LTC settings, when residents exhibit violent or physically aggressive behavior.

Among people living with Alzheimer's disease (AD), depression is the earliest observable symptom in at least one-third of cases.[12] Milder agitation may manifest early and increase in prevalence and severity with worsening of dementia, often leading to an increase in caregiver burden, greater morbidity, poorer quality of life, increased cost of care, early institutionalization, and rapid disease progression.[13] LTC staff caring for residents with depression, agitation, and other NPS often experience decreased quality of life, increased risk of injury, increased workload, lost days of work, burnout, and staff turnover.[14,15]

Background on Clinical Care for NPS

While antipsychotics have been used to treat NPS since the 1950s, people with neurodegenerative disorders were previously excluded from trials of psychotropic medications in general, and antipsychotics specifically, despite the fact that both brain changes and biological aging may impact psychotropic dosage needs and response, carrying significant risks.

In April 2005, the FDA issued a "black-box" warning for atypical antipsychotics in the treatment of NPS in older patients with dementia because of a 1.6- to 1.7-fold higher death rate compared to the placebo. In a pivotal randomized control trial (RCT) of patients with dementia who were already on first-generation or atypical (second generation) antipsychotics, the 3-year survival rate was doubled in those randomized to cease treatment compared to that of patients on antipsychotic therapy.[16] However, a large longitudinal observational study published in the September 2013 issue of the *American Journal of Psychiatry* challenged these findings by showing that **the primary correlation of adverse outcomes was the psychiatric symptomatology of dementia progression and not a result of the drugs used to treat the condition**.[17] Additionally, a 2015 study in the same journal analyzed data from the Cache County Dementia Progression Study to examine the link between clinically significant neuropsychiatric symptoms in mild Alzheimer's dementia and progression to severe dementia and death, and found that psychosis, affective symptoms, agitation/aggression, mildly symptomatic neuropsychiatric symptoms, and clinically significant neuropsychiatric symptoms were all associated with earlier death.[18] It is important to note that neurodegenerative disorders are progressive and fatal. The treatments for such diseases, whether pharmacologic or non-pharmacologic, are for symptomatic management only. While no medication has been specifically approved at this time for the treatment of agitation or other NPS in AD, a number of studies have been published with information

strong enough to provide guidance to clinicians. For example, two studies with almost identical design have shown efficacy of methylphenidate in the treatment of apathy in AD.[19,20] With regards to the treatment of agitation in AD and other dementias, there is a large amount of literature clearly showing a small, but consistent effect of atypical antipsychotics; and, studies have shown that citalopram and the combination of dextromethorphan and quinidine are safe and effective.[21,22,23]

When the appropriate population is targeted, the size of the effect is magnified, and the safety profile improved. A study by Devanand, Mintzer, and colleagues showed significant improvement in relapse rates of agitation in patients that responded to treatment with an atypical antipsychotic (risperidone).[24] These results underscore the inappropriateness of discontinuing these medications after a patient has shown a clear symptomatic response.

Pimavanserin is currently the only approved medication by the FDA for the treatment of NPS in neurodegenerative disorders. This agent is approved for the treatment of hallucinations and delusions occurring in Parkinson's Disease (PD) psychosis.[25] Other uses of psychotropics for NPS would be considered "off label," although they may be considered necessary when practicing evidence based patient-centered care. There are multiple FDA-approved indications for first-and-second-generation antipsychotics that include bipolar disorder, major depression and nausea and vomiting. Off-label usage for any psychotropic medications tend to be based on extensive experience, evidence, and some are endorsed by treatment guidelines.[26,27]

All treatment decisions should be patient-centric, however a recent Current Psychiatry Reports paper provides a comprehensive summary of recommended pharmacologic treatments for NPS:[28]

Table 1 Recommended treatments for neuropsychiatric syndromes

Neuropsychiatric syndrome	1st-line therapies*	2nd-line therapies	3rd-line therapies
Agitation in AD	Citalopram (10–30 mg/day)** Risperidone (0.5–1 mg/day)	Aripiprazole (10 mg/day) Carbamazepine (300 mg/day) Dextromethorphan/quinidine (20/10 mg BID) Olanzapine (5–10 mg/day) Quetiapine (200 mg/day) Trazodone (50–100 mg/day)	Lamotrigine (25–100 mg/day) THC (2.5–7 mg/day)
Apathy in AD	Methylphenidate (20 mg/day)	Modafinil (200 mg/day)	
Depression in AD	Citalopram (10–40 mg/day)** Escitalopram (5–20 mg) Sertraline (50–150 mg)	Aripiprazole as augmentation (2 mg–15 mg/day) Bupropion (100 mg–300 mg/day) Carbamazepine (augmentation) (300 mg/day) Duloxetine (20–60 mg/day) Fluoxetine (20–40 mg/day) Mirtazapine (7.5–30 mg/day) Paroxetine (10–40 mg/day) Quetiapine as augmentation (25–200 mg/day) Venlafaxine (37.5–225 mg/day)	Electroconvulsive therapy Tricyclic antidepressants
Depression in PD	Pramipexole (0.3–4.2 mg/day) Ropinirole (10 mg/day)	Citalopram (10–20 mg/day) Desipramine (25–75 mg/day)*** Nortriptyline (25–75 mg/day)*** Sertraline(25–50 mg/day)	Electroconvulsive therapy Bupropion (100–300 mg/day) Duloxetine (30–60 mg/day) Mirtazapine(30 mg/day) Paroxetine (10–40 mg/day) Venlafaxine (37.5–225 mg/day)
Psychosis in PD	Pimavanserin (40 mg/day)	Clozapine (6.25–50 mg/day) Quetiapine (25–100 mg/day)	Risperidone (0.5–2 mg/day) Olanzapine (5–7.5 mg/day)

*Initiation of pharmacological interventions should occur after non-pharmacological approaches, cognitive enhancers, and comprehensive assessment of medical and environmental factors has been completed

**Maximum recommended dose for citalopram in patients over the age of 60 is 20 mg/day

***TCA should not be used in patients with cognitive impairment

Since there are no disease-modifying treatments for dementia, clinicians focus on decreasing patients' suffering and improving their quality of life. The underlying cause of these behaviors may be neurobiological, an acute medical condition, unmet needs, or a preexisting psychiatric illness. Because of this complexity, treatment should begin with an assessment to rule out potentially reversible causes of NPS. These causes can range from environmental to pharmacologic. For mild to moderate NPS, short-term behavioral interventions, followed by pharmacologic interventions, are commonly used. For moderate to severe NPS, pharmacologic interventions and behavioral interventions are often used simultaneously. This stepped approach to prescribing is possible to implement, and necessary to develop clear guardrails for appropriate use of antipsychotics.

Non-Pharmacologic Approaches to NPS

After environmental and other medications are ruled out as a potential cause, turning to nonpharmacologic interventions, alone, is not standard practice. While evidence-based psychosocial (i.e., non-pharmacologic) interventions have shown some promise in managing these symptoms, they are rarely used in everyday clinical practice. CMS developed a training program and care plans to promote "person-centered high-quality care" and the use of non-pharmacologic treatment alternatives to antipsychotics.[29] Unfortunately, less than 2% of facilities consistently implement the person-centered care approaches for NPS and most staff lack the knowledge, skills, or experience to effectively implement nonpharmacologic approaches.[30-32] Such person-centered care requires resources, including reimbursement for implementation, and commitment to these goals. Additionally, the evidence for non-pharmacologic interventions has not been robust enough for payer adoption. A March 24, 2020 draft systematic evidence review by the Agency for Healthcare Research & Quality (AHRQ) found that "very little evidence supports widespread dissemination of any general care approaches for PWD [people with dementia]. This review demonstrates the need for larger, longer-term, and more rigorous studies of interventions."[33]

It is important to recognize that neuropsychiatric symptoms of dementia are clinically characterized as progressing in severity over time. On the one hand, neither health care workers nor family members want to see people with dementia over-sedated and with a poor quality of life. Conversely, the reality of needing to protect family members staff and other residents from potentially dangerous symptoms, should be recognized. Effectively diagnosing, managing or preventing behaviors that disturb and can cause harm to self and others is valuable to residents, LTC staff, family caregivers, and payers. Specific diagnostic criteria have been developed for psychosis in AD,[34] depression in AD,[35] apathy in AD and other neurodegenerative disorders[36] and agitation in cognitive disorders including AD.[37] In Parkinson's Disease (PD), criteria have been developed to include psychosis in PD and depression in PD.[38,39] Diagnostic criteria, combined with clinical guidelines, are essential to inform prescribers and to explain the use of the medication to patients, as well as professional and family caregivers. **Currently, CMS does not integrate diagnostic criteria and clinical guidelines into nursing home operator, prescriber, medical director, nursing, and surveyor trainings, or in standardized patient assessment elements (SPADEs) for the Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), Inpatient Rehabilitation Facility–Patient Assessment Instrument (IRF-PAI), or LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS).**

Quality Measure Improvement

CMS' current quality measure impacts clinical practice in unintended ways. Attempts to comply with reductions in the measure can lead to skilled nursing facilties (SNFs) denying admission and can lead to the use of medications that are outside of the antipsychotic class and go against best clinical evidence. By updating the antipsychotic utilization quality percentage to incorporate a new three-pronged documentation approach, the antipsychotic utilization quality domain will be based on evidence, treatment guidelines, and FDA-approved indications for use and will be consistent with already existing CMS Interpretive Guidelines.

The current measure fails to meet the Program-Specific Measure Needs and Priorities set forth by CMS' Center for Clinical Standards and Quality (CCSQ).[40] The measure also does not adjust for clinical rationale and it inadvertently disadvantages facilities based on size, location, and/or clinical specialty.

> *Criterion a: Measure **does not** support the Meaningful Measure Initiative by addressing a Meaningful Measure area and prioritizing outcomes measures, patient reported outcome measures (PROMs), and electronic measures when possible.*

The current measure reports the percentage of long-stay residents who are receiving antipsychotic drugs in

the target period. These reported figures represent the current number of patients receiving a certain drug class of treatment and do not account for appropriateness as defined by patient health outcomes and/or thoughtful clinical rationale. We propose building upon the antipsychotic measures collected in the RAI to better prioritize meaningful outcomes.

> *Criterion c: Measure **does not** have a strong scientific evidence base to demonstrate that the measure when implemented can lead to the desired outcomes and/or more affordable care (i.e., NQF's Importance criteria).*

The current measure lacks scientific evidence and the reported figures do not correlate with appropriate antipsychotic utilization rates in nursing homes and LTCFs. The RAI measures that Project PAUSE supports are specific to antisychotics, incorporate many clinically proven tools (like GDRs), and includes review from a resident's care team.

> *Criterion g: Measure results and performance **do not** identify opportunities for improvement.*

The current measure is limited in scope. The basic reporting of the number of residents taking antipsychotic medication(s) does not provide any information on the number of residents whose conditions require antipsychotic medication(s), nor does it provide an opportunity for a patient's care team to indicate whether or not medications are appropriately prescribed. In an effort to reduce the amount of inappropriate antipsychotic utilization rates in nursing homes and LTCFs and identify areas for care improvement, more robust information is needed. The RAI includes better patient assessment information to properly meet this criteria.

> *Criterion h: The use of this measure in a program **does** result in negative unintended consequences (**denial of treatment, limiting access to care, creating provider burden**)*

The current measure has created a multitude of negative unintended consequences. As Project PAUSE continues to work with CMS to reduce inappropriate use of antipsychotic utilization rates, the medical community has become increasingly aware of the negative impact that the current limited metric has on denying antipsychotic medications to patients with a necessary, FDA-approved indication.

The current measure also creates unnecessary burden on patients, facilities, and providers, as patient care teams are documenting more meaningful information pertaining to antipsychotic utilization in the RAI but are still subject to the reports of the nonclinical figures that CMS requires. The measure currently utilized by the National Partnership also does not adjust for clinical rationale and it inadvertently disadvantages facilities based on size, location, and/or clinical specialty.

Disadvantages Based on Facility Size

As the population of people over 65 years old continues to increase, the absolute number of patients suffering from psychosis will also continue to grow.[41] The current quality measure utilized by The Partnership indicates that "lower is better," which fails to adjust for the increasing patient population and the additional services that these patients will require as they continue to age beyond that of the current population.[42] The current measure will only continue to create situations where it may appear that a SNF is continually failing to meet care standards, when, in fact, they are adapting to the needs of a growing aging population.

Since the current measure used to determine antipsychotic utilization is calculated using a percentage of total antipsychotic utilization for long-stay residents, some nursing homes may appear to have an abnormally high rate of antipsychotic medication use. For example, a 50-bed facility that has five (5) patients diagnosed with Bipolar disorder and five (5) patients with major depressive disorder would seem to have a high number of patients inappropriately prescribed antipsychotic medications. This is because the current quality measure is based on a percentage. If a large facility had double the number of residents prescribed antipsychotic medications compared to the previous example, their quality measure would not solicit any concern from CMS, even though the facility has more individuals currently prescribed antipsychotic medications. This systematic problem disproportionately impacts patients and facilities in rural communities.

Disadvantages Based on Facility Location

Utilizing a generic percentage as a quality metric does not accurately capture the size and scope of the problem, which is evident in many rural facilities across the country.[43] Rural facilities are more likely to house a smaller number of residents, which means that any resident receiving antipsychotic medications, regardless if it is appropriate or inappropriate, has the potential to negatively impact a rural facility. This can lead to denial of care for the frailest patients living in rural communities.[44] In order to prevent undue burden on rural facilities, CMS needs to utilize more robust data to properly articulate the rate of inappropriate antipsychotic utilization rates.

Disadvantages Based on Clinical Expertise

Many nursing homes and LTCFs are beginning to specialize in treating residents with complex conditions.[45] A facility may choose to admit more patients with moderate dementia and psychotic symptoms due to management expertise. This facility may have a large percentage of patients appropriately treated with antipsychotics and, again, be disadvantaged by the use of the current quality measure since CMS looks at the total number of patients taking antipsychotic medications rather than the amount of inappropriate use. This has the unintended consequence of deemphasizing excellence in dementia and psychotic symptom care.

Alternative Quality Measure(s)

As represented through CMS' RAI User Manual, there are current federal and clinical standards in place to help mitigate inappropriate antipsychotic usage. Medication management is a clinical tool centered around the unique pharmacologic expertise of a consultant pharmacist and a patient's primary health care provider to tailor a patient's medication usage to their individual needs.[46] Medication management standards are published in the State Operations Manual (SOM), which provides each individual state and CMS with regulatory oversight and authority.[47] PAUSE urges CMS to incorporate uniform language when measuring antipsychotic utilization rates and change the Partnership's antipsychotic measure to include antipsychotic utilization as determined through the RAI User Manual (see figure 4). PAUSE also urges CMS to further promote quality excellence through incorporating consultant pharmacist's review of antipsychotic medications in the documentation of antipsychotic use. In the above example, accurate documentation of medication management and medication regimen review would be incorporated into the quality measure. PAUSE firmly asserts that this process is the best multifaceted approach to empower CMS and other authorities with the information needed to determine if antipsychotic utilization is inappropriate without threatening patient access to medically necessary medications.

This new documentation would create a representative percentage of antipsychotic utilization through utilizing:

D. (0) GDR has not been documented by the advanced practice practitioner and pharmacist as clinically contraindicated or documented the use and dose as clinically appropriate +

The total number of long stay residents who are in a nursing home for greater than 100 days during the reporting interval [48]

N0450. Antipsychotic Medication Review	
Enter Code ☐	**A. Did the resident receive antipsychotic medications since admission/entry or reentry to the prior OBRA assessment, whichever is more recent?** 0. **No** – Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E 1. **Yes** – Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted? 2. **Yes** – Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted? 3. **Yes** – Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?
Enter Code ☐	**B. Has a gradual dose reduction (GDR) been attempted?** 0. **No** → Skip to N0450D, documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* 1. **Yes** → Continue to N0450C, Date of last attempted GDR
	C. Date of last attempted GDR: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year
Enter Code ☐	**D. Documented GDR as clinically contraindicated or documented use of the drug and dose as clinically appropriate** 0. **No** – GDR has not been documented by *BOTH physician and pharmacist* as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* → Skip N0450E Date *physician or pharmacist* documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* 1. **Yes** – GDR has been documented *by BOTH physician and pharmacist* as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* → Continue to N0450E, Effective date of documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate*
	E. Date of documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate:* ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

A [SUM D. (0)]

B [SUM of long stay residents who are in the nursing home for greater than 100 days during the the reporting interval]

This new percentage will more closely reflect potential inappropriate antipsychotic usage in nursing homes. Under this proposed measure, advanced practice practitioners (APPs) would continue to document their clinical rationale for prescribing an antipsychotic medication and the facility's consultant pharmacist would continue to document gradual dose reduction (GDR) and medication regimen review (MRR) information. The Minimum Data Set (MDS) coordination would document that the APP and the consultant pharmacist performed their required reviews. These checks and balances will enforce patient centered care and quality data surrounding the use of antipsychotics. Any concern regarding an uneccessary use of a medication would still be investigated and reported by the surveyor, which is current practice. Should a state surveyor not find the three-pronged documentation certifying antipsychotic utilization in a facility, the facility would be considered to be inappropriately prescribing antipsychotic medications. The new metric would more accurately reflect the percentage of residents that are potentially inappropriately treated with an antipsychotic.

Further addressing documentation as part of the antipsychotic use measure will also address other shortcomings of the current quality measure that do not allow CMS to collect all information pertaining to antipsychotic utilization in nursing homes. It will also allow for patient care to adapt to new evidence and new and future FDA approvals that have antipsychotic compounds to treat behaviors and psychosis that are in late phases of development.

Patients and health care practitioners can be limited in taking advantage of new evidence or of advancements in treatments under the current quality metric. This forces health care practitioners to decide between what is best for patients and what best addresses the current CMS quality measures.

Thank you for the opportunity to help improve patient care in America's nursing homes. If you have any questions, would like to join our effort, or require additional information, please contact Veronica Charles at vcharles@ascp.com. We look forward to working with you.

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Appendix 1

Figure 1

Percent of residents who receive an antipsychotic medication	This measure reports the percentage of long-stay residents who are receiving antipsychotic drugs in the target period. Reducing the rate of antipsychotic medication use has been the focus of several CMS initiatives.

Figure 2: Tables of FDA-Approved Indications for First-Generation Antipsychotics[49]

Generic Name	Indications	Age Group for Which Approved
Chlorpromazine	Schizophrenia	Adults and children (1–12 years)
	Bipolar disorder (mania)	
	Severe behavioral problems	
Droperidol	Agitation	Adults and children
Fluphenazine	Psychotic disorders	Adults
Haloperidol	Schizophrenia	Adults
	Tourette syndrome	
	Hyperactivity	
	Severe childhood behavioral problems	
Loxapine	Schizophrenia	Adults and children ≥12 years
Perphenazine	Schizophrenia	Adults and children ≥12 years
Pimozide	Tourette syndrome	Adults and children ≥12 years
Prochlorperazine	Schizophrenia	Adults and children >2 years and >20 pounds
	Generalized nonpsychotic anxiety	Adults
	For treatment of nausea/vomiting	
	For the treatment of intractable, severe migraine unresponsive to other therapies	
Thiothixene	Schizophrenia	Adults and children ≥12 years
Thioridazine	Schizophrenia	Adults and children
Trifluoperazine	Schizophrenia	Adults and children ≥6 years
	Generalized nonpsychotic anxiety	Adults

FDA approved indications; updated 03/22/2018

Figure 3: Tables of FDA-Approved Indications for Second-Generation Antipsychotics[46]

Generic Name	Indications	Age Group for Which Approved
Aripiprazole	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed) monotherapy or adjunctive to lithium or valproate	Adults and children (10–17 years)
	Adjunctive treatment of major depressive disorder	Adults
	Irritability Associated with autistic disorder	Children (6–17 years)
	Acute treatment of agitation	Adults
Asenapine	Acute schizophrenia	Adults
	Bipolar disorder type 1 (manic/mixed)	
Clozapine	Treatment resistant schizophrenia	Adults
	Reduce the risk of suicidal behavior in younger patients with schizophrenia	
Iloperidone	Acute schizophrenia	Adults
Olanzapine	Schizophrenia Bipolar disorder (manic/mixed)	Adults and adolescents (13–17 years)
	Bipolar disorder	Adults
	Treatment resistant depression	
	Agitation associated with schizophrenia and bipolar I mania	
Paliperidone	Schizophrenia	Adults
	Schizoaffective disorder	
Quetiapine	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (acute manic)	Adults, children, and adolescents (10–17 years)
	Bipolar disorder (depression)	Adults
	Bipolar disorder (maintenance)	
	Adjunctive therapy for major depressive disorder	
Risperidone	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed)	Adults and adolescents (10–17 years)
	Irritability associated with autism	Children (5–16 years)
Ziprasidone	Schizophrenia	Adults
	Bipolar disorder (manic/mixed)	
	Bipolar disorder (maintenance)	
	Acute agitation in patients with schizophrenia	
Pimavancerin	Treatment of Hallucinations and Delusions associated with Parkinson's Disease Psychosis	Adults
Brexpiprazole	Schizophrenia	Adults
	Adjunctive treatment of major depressive disorder	
Lumateperone	Schizophrenia	Adults
Cariprazine	Treat Bipolar depression and the short term treatment of manic or mixed episodes that happen with bipolar 1 disorder	Adults
Lurasidone	Treatment of major depressive episode associated with bipolar I disorder (bipolar depression)	Adults and children (10 to 17 years)
	Adjunctive treatment with lithium or valproate with bipolar depression	Adults

FDA approved indications; updated 03/22/2018

Figure 4: N0450: Antipsychotic Medication Review

N0450. Antipsychotic Medication Review	
Enter Code [ ] **Enter Code** [ ]	**A. Did the resident receive antipsychotic medications since admission/entry or reentry to the prior OBRA assessment, whichever is more recent?** 0. **No** – Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E 1. **Yes** – Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted? 2. **Yes** – Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted? 3. **Yes** – Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?
	B. Has a gradual dose reduction (GDR) been attempted? 0. **No** → Skip to N0450D, Physician documented GDR as clinically contraindicated 1. **Yes** → Continue to N0450C, Date of last attempted GDR
	C. Date of last attempted GDR: [ ][ ] - [ ][ ] - [ ][ ][ ][ ] Month Day Year
Enter Code [ ]	**D. Physician documented GDR as clinically contraindicated** 0. **No** – GDR has not been documented by a physician as clinically contraindicated → Skip N0450E Date physician documented GDR as clinically contraindicated 1. **Yes** – GDR has been documented by a physician as clinically contraindicated → Continue to N0450E, Date physician documented GDR as clinically contraindicated
	E. Date physician documented GDR as clinically contraindicated: [ ][ ] - [ ][ ] - [ ][ ][ ][ ] Month Day Year

PROJECT pause

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