Psychotropic Stewardship

Navigating Phase 3 Guidance to Individualize Pharmaceutical Care

Elizabeth Hidlebaugh, MD

Geriatrician, AMDG Naples 100 Senior Concierge & Consulting

Rick Foley, PharmD, CPh, FASCP, BCGP

Senior Manager, Clinical Services, Omnicare

Dr Hidlebaugh has no disclosures

Dr Foley is a full-time employee of CVS/Omnicare

Learning Objectives

Understand Phase 3 guidance changes with respect to psychotropic medications

Identify and develop a plan for addressing potential psychotropic medication irregularities

Design and implement a psychotropic stewardship program

Summarize keys to success to work as a team in a psychotropic stewardship program

Case Study

JM is a 78 yo F admitted today for rehab s/p ORIF due to a ground-level fall at her ALF sustained one week ago.

Discharge Medication List

Medication	Diagnosis
Lisinopril 20mg QD	Hypertension
Valproic Acid 500mg BID	Seizures
Gabapentin 300mg BID	Anxiety
Quetiapine 25mg HS	Schizophrenia
Metformin 500mg BID	Diabetes
Metoprolol XL 50mg QD	Hypertension
Donepezil 10mg QD	Alzheimer's Disease
Atorvastatin 40mg QD	Hyperlipidemia
Mirtazapine 15mg HS	Anorexia
Clonidine 0.1mg Q8h PRN SBP > 140	Hypertension
Amlodipine 10mg once daily	Hypertension
Citalopram 20mg once daily	Depression
Aspirin 81mg once daily	Hx MI

- Sentinel medications
- Sentinel diagnoses
- Where do we need more information?

Alzheimer's Disease & Related Dementias

- All-cause dementias: cognitive or behavioral symptoms that
  - Interfere with the ability to function at work or at usual activities; and
  - Represent a decline from previous levels of functioning and performing; and
  - Are not explained by delirium or major psychiatric disorder;
  - Cognitive impairment is detected and diagnosed through history taking and an objective cognitive assessment
  - The cognitive or behavioral impairment involves a minimum of 2 domains:
    1) impaired ability to acquire and remember new information;
    2) impaired reasoning and handling of complex tasks, poor judgement;
    3) impaired visuospatial abilities;
    4) impaired language functions;
    5) changes in personality, behavior, or comportment

- **Mild cognitive impairment** does not interfere with functioning

Alzheimer’s Disease & Related Dementias

- **Alzheimer's Disease dementia** diagnosed when:
  - Insidious onset
  - Clear-cut history of worsening of cognition; and
  - The initial and most prominent cognitive deficits are evident on history and examination in one of the following categories:
    - Amnestic presentation (learning and recall of recently learned information, and at least one other domain impairment)
    - Non-amnestic presentation: language (word-finding + 1 domain), visuospatial (spatial cognition + 1 domain), executive dysfunction (impaired reasoning, judgement, problem solving +1 domain)
  - No evidence of other disease (Lewy body, cerebrovascular disease, etc)

Alzheimer's Disease & Related Dementias

- **Vascular Dementia**
  - Major cerebrovascular event -> stepwise decline/fluctuating course
  - Vs significant subcortical microvascular events -> gradual onset, slowly progressive
    - Deficits particularly in speed of information processing, complex attention and/or frontal-executive functioning + early gait disturbance/falls, or early urinary symptoms, or personality and mood changes

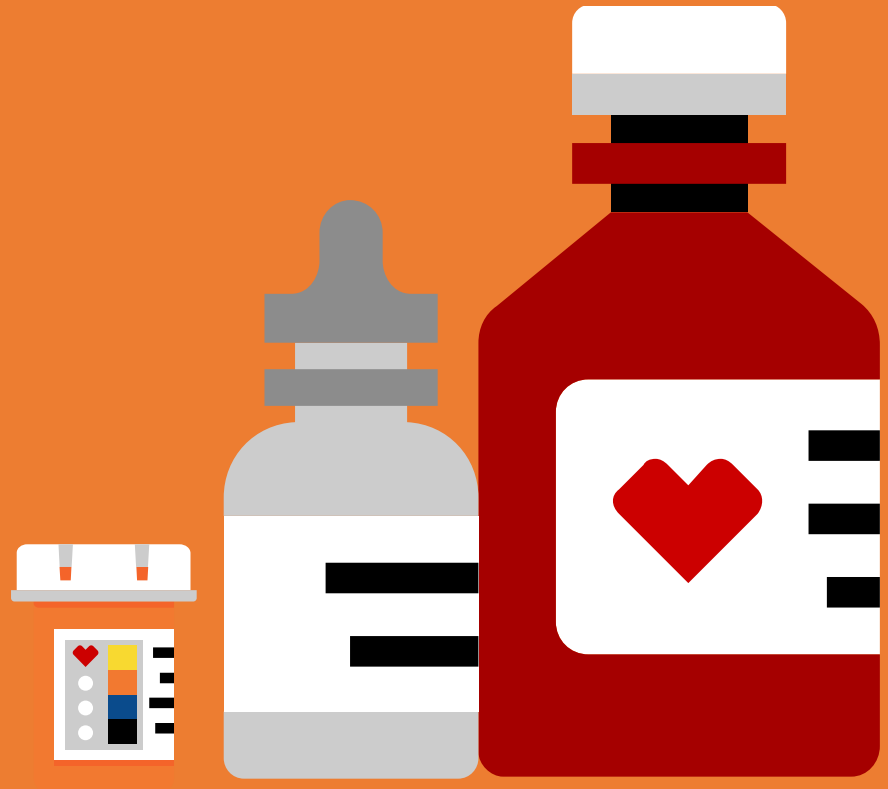
Alzheimer's Disease & Related Dementias

- **Dementia with Lewy bodies**
  - Fluctuating cognition/attention/alertness, well formed visual hallucinations, REM sleep behavior disorder, parkinsonism
  - Cognitive impairments appear before or around same time as parkinsonism

- **Frontotemporal dementia**
  - Behavioral variant: at least 3 of the following - behavioral disinhibition, apathy, loss of empathy, ritualistic behavior, hyperorality, executive dysfunction with relative sparing of memory and visuospatial functions
  - Primary progressive aphasia: difficulty with language, aphasia
    - Logogenic variant PPA, Non-fluent variant PPA, Semantic variant PPA

Objectives of Revised Guidance

- **Pharmaceutical Care and Services**
  - Evaluate psychopharmacologic use and Gradual Dose Reduction of medications that can affect brain activity
  - Document the medical history of an accurate psychiatric diagnosis



F658 and F659: Comprehensive Person-Centered Care Plans

Guidance Overview

- New guidance on care planning and services provided, reporting practitioners not adhering to professional standards of quality

Rationale

- F658: CMS documented incidents of situations of potential misdiagnosis of schizophrenia, allowing for antipsychotic use and exclusion of resident's data from long-stay AP measures
- F659: Services provided and arranged “in accordance with the residents plan of care”

Implications for Non-Adherence

- Referral to State Medical Boards or Board of Nursing

Recommended Facility Action

- Review and update current policies and procedures
- Communicate changes with residents, families, staff and practitioners
- Confirm documentation of psychiatric diagnosis from past medical history

Common Antipsychotics

Haldol (haloperidol)

Latuda (lurasidone)

Risperdal (risperidone)

Seroquel (quetiapine)

Zyprexa (olanzapine)

Potential Approved (on-label) Uses

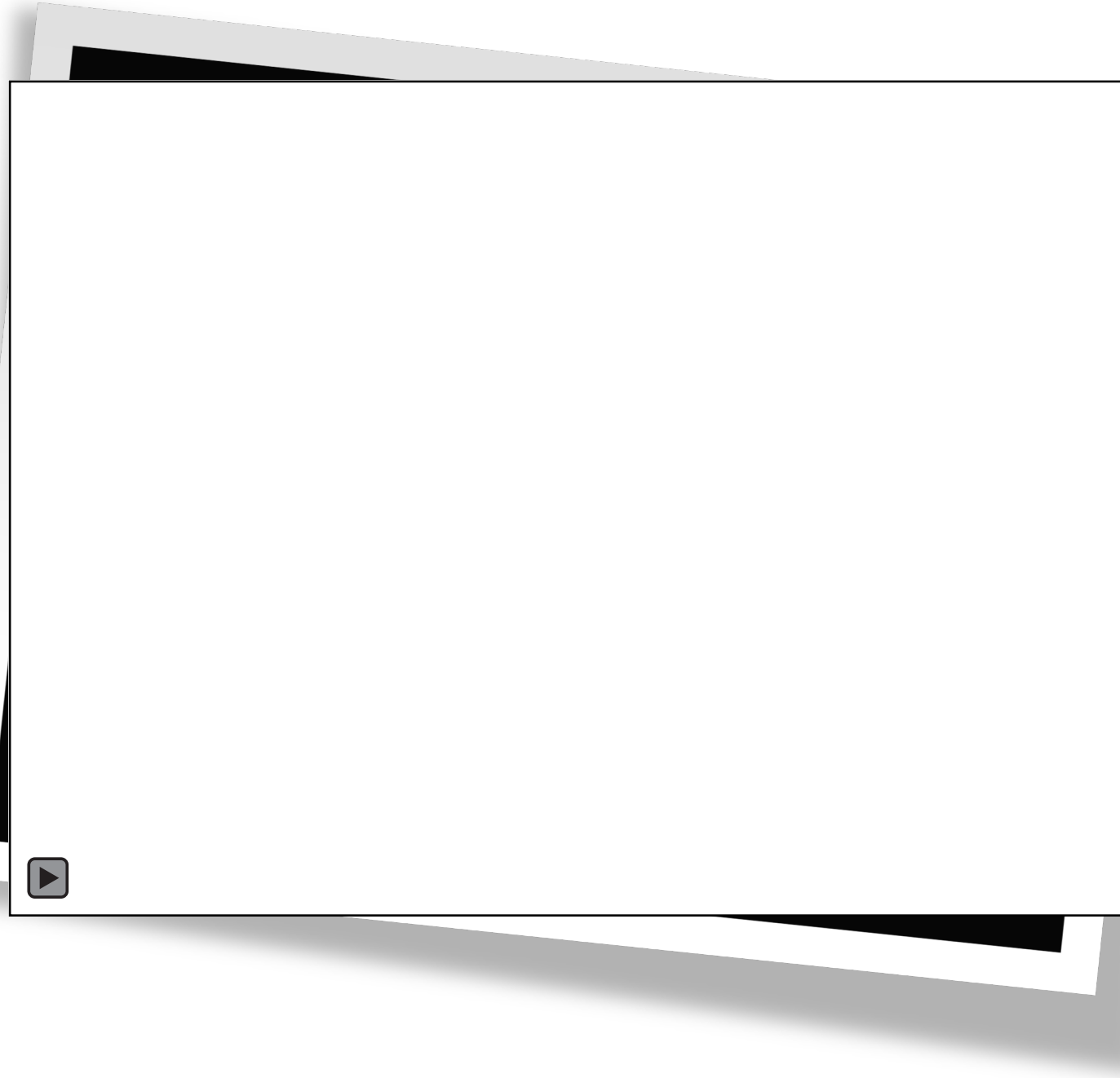
- Schizoaffective Disorder
- Schizophrenia
- Bipolar I Disorder
- Bipolar Depression
- Major Depressive Disorder

*****FDA-approved indications vary. Refer to prescribing information available at: https://dailymed.nlm.nih.gov/dailymed/**

Considerations for Adequate Indication for Use

Diagnosis **alone** may **not** warrant treatment with antipsychotics, but treatment may be justifiable when using a person-centered approach, especially when:

- Behavioral symptoms pose a **danger** to the resident or others
- Multiple attempts at **non-pharmacological approaches** failed to alleviate dangerous or distressful behavior
- The expressed behaviors are **distressful to the resident** (e.g., hallucinations)
- Symptoms returned following gradual dose reduction



Case for Adequate Indication of Use

- 78 yo M with significant history of dementia, CAD, hearing loss
- Admitted to memory care ALF due after hospitalization for agitation- on quetiapine 50 mg TID, memantine 5 mg daily
- Resident calm, no agitation -> slowly dose reduced until stopped
- Exhibited sexually inappropriate behaviors (bringing female residents into room and performing sexual acts, removing clothes)

Case for Adequate Indication of Use

- Started on aripiprazole 10 mg -> increased to 20 mg
- Memantine stopped (after quetiapine)
- Multiple interdisciplinary meetings: Director of nursing concerned about change from quetiapine to aripiprazole
  - Patient with unexplained LE edema and hyponatremia -> improved off of quetiapine
  - Started sertraline 25 mg, finasteride 5 mg, and medroxyprogesterone 2.5 mg daily
  - Wife was calling him from out of state often proceeding his behaviors

Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs

Guidance Overview

- Facility may use LTC Pharmacist generated reports for QAPI on utilization of certain drug classes, allowing for trend identification which may prevent ADRs.
- Updated guidance stating that the medical record must show documentation of the “diagnosed condition” for utilization of prescribed psychotropics.
- CMS is also providing a list of other medication classifications for medications that affect brain activity and indicates that these fall under psychotropic requirements when being used as a substitute for another psychotropic rather than approved indication.
- CMS provides guidance regarding GDR to minimize withdrawal and meeting compliance with GDR requirements.

Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs

Recommended Facility Action

- Review current policy and procedures
- Communicate regulatory changes with staff, family members, practitioners
- Utilize QAPI tracking tools provided by the consultant pharmacists as part of monthly and quarterly reporting
- Provide appropriate and documented diagnosis for psychotropic drug use
- Review the use of non-psychotropic medications that affect brain activity and document accordingly with emphasis on “substitute” medications as defined by CMS

F758

Psychotropic Drugs

New Language

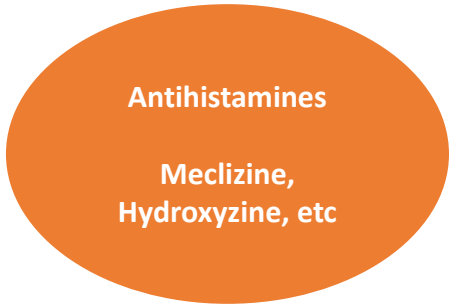
- Use of psychotropic medications, other than antipsychotics should not increase when efforts to decrease antipsychotic medications are being implemented.

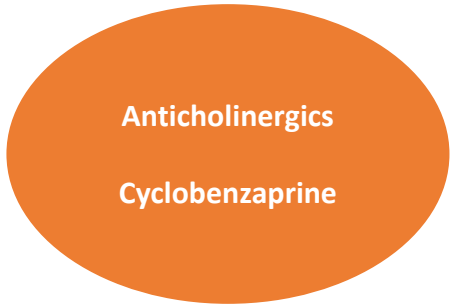
- Risks are still evident with all psychotropics, regardless of their use (e.g., nausea, insomnia, itching)

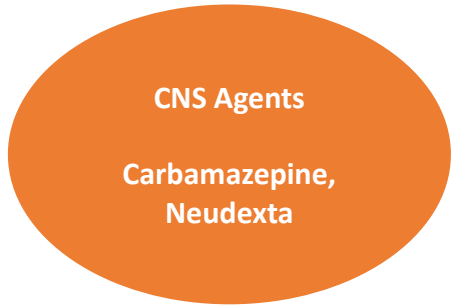
- Requirements that pertain to psychotropic drugs apply to the four categories (antipsychotic, anxiolytic, antidepressant, sedative-hypnotic) without exception

Non-Psychotropic Medications

- Medications that are not normally categorized as psychotropic medications can also affect brain activity and should not be used as a replacement for another psychotropic medication unless prescribed with a documented clinical indication consistent with clinical standards of practice.
- The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather for the original or approved indication







Discharge Medication List

Medication	Diagnosis
Lisinopril 20mg QD	Hypertension
Valproic Acid 500mg BID	Seizures
Gabapentin 300mg BID	Anxiety
Quetiapine 25mg HS	Schizophrenia
Metformin 500mg BID	Diabetes
Metoprolol XL 50mg QD	Hypertension
Donepezil 10mg QD	Alzheimer's Disease
Atorvastatin 40mg QD	Hyperlipidemia
Mirtazapine 15mg HS	Anorexia
Clonidine 0.1mg Q8h PRN SBP > 140	Hypertension
Amlodipine 10mg once daily	Hypertension
Citalopram 20mg once daily	Depression
Aspirin 81mg once daily	Hx MI

Is a GDR required?

MEDICATION	DIAGNOSIS	GDR NEEDED?
Olanzapine	Schizophrenia	Yes
Lorazepam	Seizures	Yes
Duloxetine	Pain	Yes
Mirtazapine	Anorexia	Yes
Prochlorperazine	Nausea	**Yes**
Divalproex	Seizures	No
Divalproex	Mood Disorder	**Yes**
Gabapentin	Pain	No
Gabapentin	Anxiety	**Yes**
Meclizine	Vertigo	No
Meclizine	Anxiety	**Yes**

Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs- GDR and Required Monitoring

Gradual Dose Reduction

"Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence."

Required Monitoring

"If the record shows evidence of prescribing multiple psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale."

F758: Psychotropic Drugs - Summary of PRN Orders for Psychotropics*

	PRN NON-ANTIPSYCHOTIC PSYCHOTROPICS	PRN ANTIPSYCHOTICS
TIME LIMITATION	14 days	14 days
EXCEPTION	Order may be extended beyond 14 days if the prescriber believes it is appropriate to extend the order	None
REQUIRED ACTIONS	Prescriber should document the rationale for the extended time period in the medical record and indicate a specific duration	If the prescriber wishes to write a new order for the PRN antipsychotic, they must first evaluate the resident to determine if the new order is appropriate

* No change from previous guidance

F757/F758- Investigating Concerns Relating to MRR, Unnecessary Medications and Psychotropic Medications- Psychosocial Harm

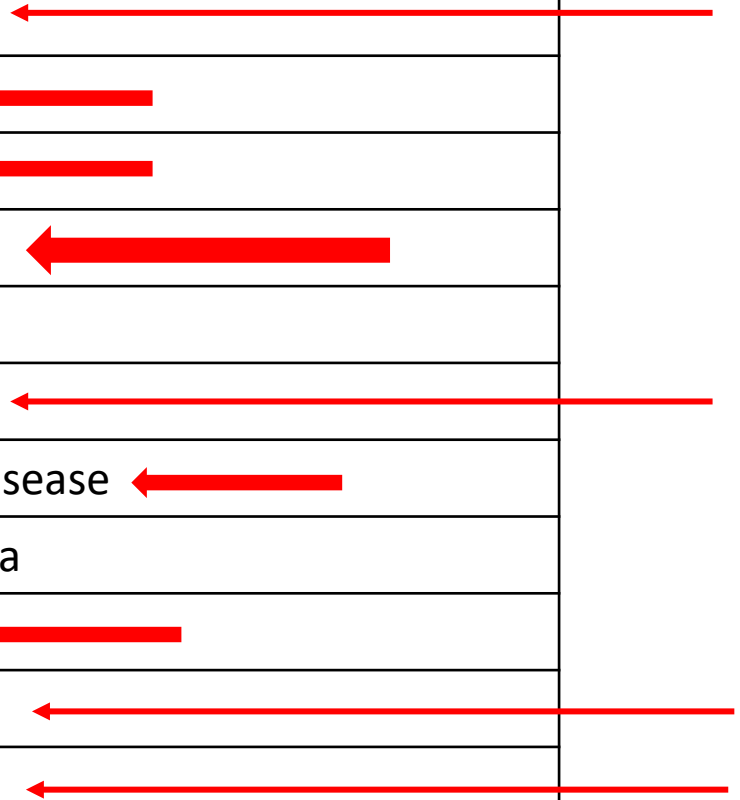
Surveyor interview to determine potential psychosocial harm due to side effects of medication therapy (e.g., sedation, lethargy, agitation, mental status changes, behavioral changes)

Did these side effects:

- affect the resident's abilities to perform activities of daily living or interact with others?
- cause the resident to withdraw or decline from usual social patterns?
- show that the resident has decreased engagement in activities?
- cause a diminished ability to think or concentrate?

Discharge Medication List

Medication	Diagnosis
Lisinopril 20mg QD	Hypertension
Valproic Acid 500mg BID	Seizures
Gabapentin 300mg BID	Anxiety
Quetiapine 25mg HS	Schizophrenia
Metformin 500mg BID	Diabetes
Metoprolol XL 50mg QD	Hypertension
Donepezil 10mg QD	Alzheimer's Disease
Atorvastatin 40mg QD	Hyperlipidemia
Mirtazapine 15mg HS	Anorexia
Clonidine 0.1mg Q8h PRN SBP > 140	Hypertension
Amlodipine 10mg once daily	Hypertension
Citalopram 20mg once daily	Depression
Aspirin 81mg once daily	Hx MI



Monitoring for Adverse Effects of Antipsychotics

- Observational monitoring should be ongoing. Other monitoring should be performed upon initiation, at least every 3 months, with any dose changes, following discontinuation, and as clinically appropriate.
- **Laboratory Monitoring and Vital Signs**
  - Weight, blood pressure, blood glucose
  - Lipid panel
  - Electrocardiogram at baseline and as clinically indicated
- **Observational Monitoring -** Observe for extrapyramidal symptoms (EPS) and consider the use of objective rating tools such as an AIMS assessment.
    - **Parkinsonism**: Tremors, drooling, muscle rigidity, shuffled gait
    - **Dystonia**: Painful, acute, muscle contracture commonly in the neck, eyes, and trunk
    - **Akathisia**: Restlessness, fidgeting, pacing, rocking

AIMS = Abnormal Involuntary Movement Scale

Jankelowitz SK. Treatment of neurolept-induced tardive dyskinesia. Neuropsychiatr Dis Treat. 2013; 9:1371-1380.
Prescribing information obtained from DailyMed.
Stroup TS et al. Management of common adverse effects of antipsychotic medications. World Psychiatry. 2018; 17(3):341-356.

Potential Adverse Effects of Antipsychotics

General	Dry mouth, constipation, increased falls, sedation/drowsiness
Cardiovascular	Irregular heartbeat, changes in blood pressure
Metabolic	Weight gain, elevated cholesterol, elevated blood glucose
Neurologic	Uncontrollable movements, tardive dyskinesia, stroke, increased suicidality

Identifying Overutilization and Misuse of Psychotropic Medications

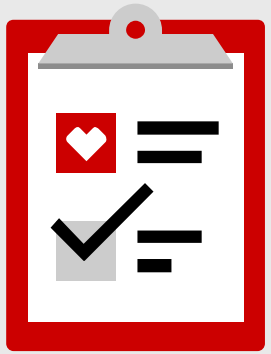
It is important to recognize when a patient may benefit from a reduction in use of psychotropic medications in order to prevent or reduce the risk of adverse effects related to their use.

What Overutilization and Misuse Looks Like

- **Oversedation -** Resident requires assistance to wake up or stay awake
- **Toxicity of medications -** Elevated serum concentrations of medications
- **Inappropriate use or indication**
  - Anxiolytics and antipsychotics used for sleep
  - Not utilizing nonpharmacologic therapy
- **Duplicate therapy -** Multiple antidepressants without a clear rationale

Steps to Reduce the Risk of Psychotropic Use

It is important to develop a plan of care and share that plan with individuals, family, and other caregivers.



- **Establish the goals of therapy and how they will be measured and documented**
  - Develop and reevaluate non-drug interventions (e.g., CBT, music, companionship)
  - Educate individuals and caregivers of potential side-effects and what to look for (e.g., falls, mood changes)
  - Formulate a plan for periodic reevaluation, including discussions regarding gradual dose reductions where appropriate

CBT = cognitive behavioral therapy

Prescribers Initial Steps to Reduce Psychotropic Use

New admission:

- Pay particular attention to psychotropic medications & why prescribed
- Devote a follow up visit to gathering more information, determining appropriateness, establishing non-pharmacologic management
- Enlist a family member/caregiver to communicate patient preferences, likes/dislikes to staff to help with non-pharmacologic management
- Reminder to reassess needed psychotropic medications in 1 or 2 weeks, etc.

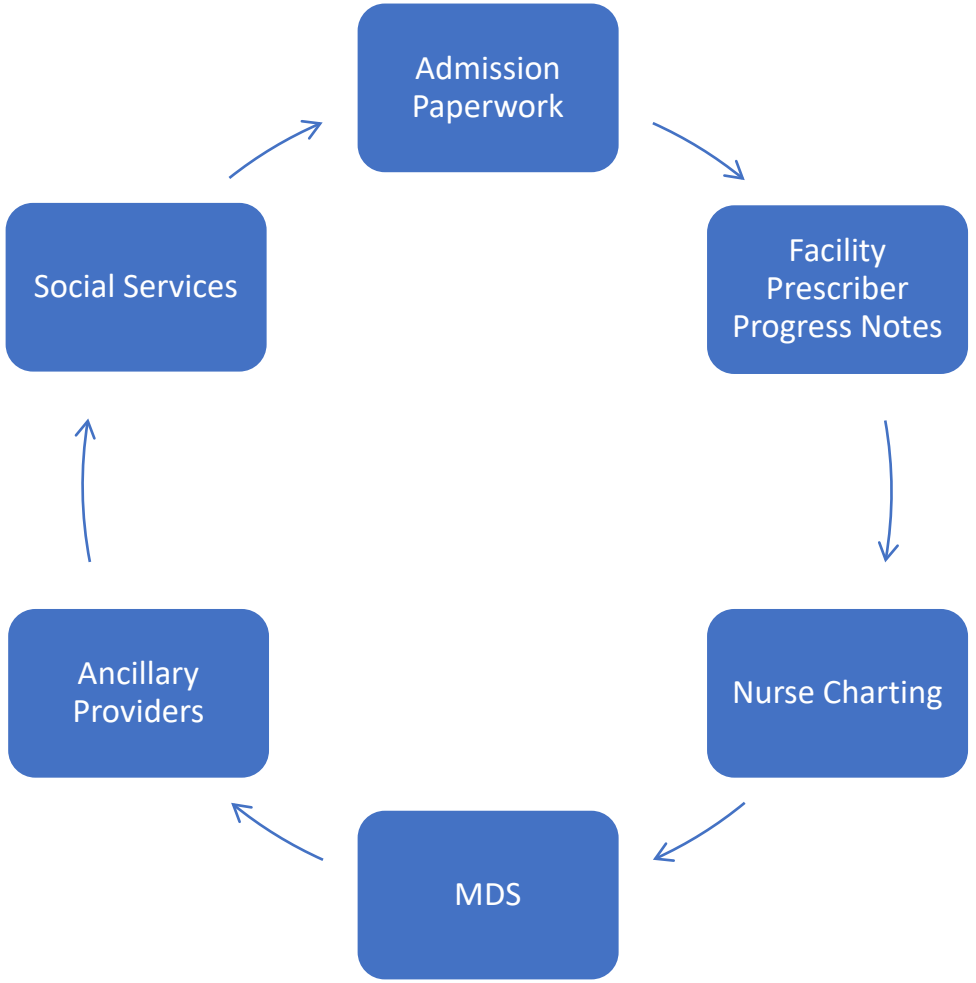
Prescribers Initial Steps to Reduce Psychotropic Use

Long term care resident:

- At monthly or q2monthly routine visits, set aside few minutes to focus on psychotropics
- Inquire with CNAs, nursing staff, activities staff how patient is doing behaviorally, side effects
- Why -> How long -> What has improved, what hasn't -> Can we dose reduce/taper/stop -> If yes, set time for follow up -> If no, set time to reassess

Development of a Psychotropic Stewardship Program

- Comprehensive admission medication review
- Education of staff (prescribers, nursing, CNAs) of documentation requirements
- Education of caregivers and family members
- Development of psychotropic stewardship meeting involving all disciplines
- QAPI



Keys to Success to a Psychotropic Stewardship Program

- Regular meetings (biweekly or monthly)
- Bring everyone to the table (medical director, director of nursing, pharmacists, CNA representative, activities director)
- Make Phase 3 requirements clear (remind everyone of regulations quarterly and when new prescribers brought on)
- Make roles clear, have follow up plan
- Everyone’s voice, in and out the meeting, is important
- If medication tapering/stopping not successful or possible, pharmacists can help keep prescribers accountable for documenting
- Celebrate wins

Pearls

- Psychotropic medications have consequences that providers must be aware of regardless of regulatory consequences
- Communicate with your consultant pharmacist and ensure they are completing thorough admission medication reviews. This is especially impactful in facilities with high Med-A populations.
- When determining the appropriateness of a dose reduction, make use of collateral information, including but not limited to, hospital H&P, previous admissions, potential prescribing cascades, psycho-social influences
- ALL PRN psychotropics require a stop date, regardless of indication. PRN antipsychotics CANNOT be auto-renewed and require direct evaluation by the prescriber.
- Have regular psychotropic stewardship program meetings with everyone in the care team- help keep each other accountable with appropriate documentation

References

- McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimers Dement*. 2011;7(3):263-269. doi:10.1016/j.jalz.2011.03.005
- Sachdev P, Kalaria R, O'Brien J, et al. Diagnostic criteria for vascular cognitive disorders: a VASCOG statement. *Alzheimer Dis Assoc Disord*. 2014;28(3):206-218. doi:10.1097/WAD.0000000000000034
- Yamada M, Komatsu J, Nakamura K, et al. Diagnostic Criteria for Dementia with Lewy Bodies: Updates and Future Directions. *J Mov Disord*. 2020;13(1):1-10. doi:10.14802/jmd.19052
- Bott NT, Radke A, Stephens ML, Kramer JH. Frontotemporal dementia: diagnosis, deficits and management. *Neurodegener Dis Manag*. 2014;4(6):439-454. doi:10.2217/nmt.14.34
- CMS Appendix PP: State Operations Manual. https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf. Accessed Sept 2023
- Jankelowitz SK. Treatment of neurolept-induced tardive dyskinesia. Neuropsychiatr Dis Treat. 2013; 9:1371-1380.
- Stroup TS et al. Management of common adverse effects of antipsychotic medications. World Psychiatry. 2018; 17(3):341-356.

Questions?