Antipsychotic Medication Quality Assurance Guidance

Overview

The Centers for Medicare & Medicaid Services (CMS) enhanced oversight on antipsychotic medication use in nursing homes throughout the last decade. Antipsychotic use in older adults can be detrimental to their overall health and well-being and used only when clinically appropriate. Antipsychotic measures in nursing home providers are also publicly available and may determine if individuals seek placement in your community. Ensuring compliance with the federal regulations and reducing the use of antipsychotics is crucial to those you serve.

Nursing homes should use this tool in conjunction with the Antipsychotic Medication Quality Assurance Worksheet to aid in compliance with both antipsychotic medication use regulations and quality assurance processes. These tools are best used by clinical representation of the Quality Assurance and Process Improvement (QAPI) team. Monitoring frequencies may vary depending on the topic, the identified error percentage, and action plan. For example, if you identify that care plans for all residents using antipsychotic medications lack information on targeted behaviors you may conduct the monitor monthly until all care plans are compliant and then adjust the monitor frequency for ongoing compliance.

Monitoring Guidance

A1 = Numerator. Adequate indication for use is defined in Appendix PP as the identified, documented, clinical rationale for administering a medication that is based upon an assessment of the resident's clinical condition and therapeutic goals, and after any other treatments have been deemed clinically contraindicated. For psychotropic medications, without documentation in the record explaining that the practitioner has determined that other treatments have been deemed clinically contraindicated, the indication for use is inadequate. Also, adequate indication for use means that the medication administered is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Diagnoses alone do not necessarily warrant the use of psychotropic medication, and they may be indicated if:

- Behavioral symptoms present a danger to the resident or others.
- Expressions or indications of distress that are significant distress to the resident.

- If not clinically contraindicated, multiple nonpharmacological approaches have been attempted, but did not relieve the medical symptoms which are presenting a danger or significant distress; and/or
- A gradual dose reduction (GDR) was attempted, but clinical symptoms returned.

A3 = Numerator. Adverse consequences or actions refer to unwanted, unintended, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (such as medication-medication, medication-food, medication-disease).

Adverse drug reaction refers to a form of adverse consequences and may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

Note: Providers may use various methods for monitoring adverse consequences/drug reactions. The nursing home regulations don't require a specific format (such as including in the MAR/TAR). However, there should be a method for documenting when adverse consequences are identified (such as documenting by exception). Staff should be knowledgeable about common adverse consequences that may occur based on the drug type and how to react when they are identified (for example, if a resident has excessive sedation, the nurse should contact the prescriber of the medication and discuss the sedation, impact on the resident's overall wellbeing and options for moving forward with treatment.

A5 = Numerator. Behavioral interventions refer to individualized, nonpharmacological approaches to care that are provided as part of a supportive physical and psychosocial environment, directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial well-being.

Nonpharmacological approaches are determined by evaluating the resident's physical, behavioral, mental, and psychosocial signs and symptoms to identify and rule out any underlying medical conditions, including the assessment of relative benefits and risks, and the preferences and goals for treatment. The use of nonpharmacological approaches must be attempted, unless clinically contraindicated, to minimize the need for psychotropic medications, use the lowest possible dose, or discontinue the

medications. The residents' medical record should include documentation of this evaluation and the rationale for chosen treatment options.

A7 = Numerator. This number represents the number of errors identified when the resident's record is reviewed for documentation supporting the resident's right to informed decision making regarding use of antipsychotic medication. Appendix PP does not dictate the method that you must use to document informed decision making. However, the Illinois Department of Public Health requires that you utilize a department developed informed consent document. For federal compliance, documentation of informed decision making must include:

- Who was notified (i.e. resident or alternate decision maker)
- Date/time (must be done prior to initiating or increasing a psychotropic medication)
- Benefits of taking the medication
- Risks of taking the medication
- Alternatives to medication use
- Black box warnings for antipsychotic medication use
- What option the resident, or their alternate decision maker chose

A9 = Numerator. This number represents the number of errors identified in gradual dose reduction (GDR) requirements. Accurate GDR procedures must include:

- Appropriate request for the GDR from the consulting pharmacist.
- Timely response from the prescribing physician.
- Implementation of the physician's directions.
- If a GDR was not conducted, the physician must document appropriate supporting clinical rationale.

Appropriate request for the GDR from the consulting pharmacist

A gradual dose reduction (GDR) is defined as a stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

A GDR must be attempted unless it is clinically contraindicated to discontinue psychotropic drug use. The purpose of the required GDR is to find an optimal dose or to determine whether continued use of the medication benefits the resident or could have dangerous side effects. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying cause of the original target symptoms have been resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

The time frame and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting

medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacological characteristics of the medications. Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom reoccurrence. Appendix PP references the American Psychiatric Association's Guidelines and Implementation which provides recommendations that patient's with dementia who show adequate response of behavioral/psychological symptoms to treatment with an antipsychotic drug, an attempt to taper and withdraw the drug should be made within 4 months of initiation, unless the patient experienced a recurrence of symptoms with prior attempts at tapering of antipsychotic medication. Assessment of symptoms should occur at least monthly during the taper for at least 4 months after medication is discontinued to identify signs of recurrence and trigger a reassessment of the benefits and risks of antipsychotic treatment.

Timely response from the physician is not defined in the regulations, however, providers should review their internal policies and procedures and decide what is reasonable. If the resident's physician has not responded to the GDR request, nurses should follow up as they would with other communication to the physician. When an order is provided to reduce the medication, nurses must ensure that it is transcribed appropriately and follow up monitoring is completed on whether the dose reduction triggers symptom return.

Documentation should include:

- The date of the GDR attempt, the outcome of the dose reduction, and the plan regarding future GDR attempts.
- Physician documentation should contain the rationale for why GDR attempts are clinically contraindicated for the resident.

A11 = Numerator. This number represents the number of records reviewed that did not follow the PRN or as needed prescribing requirements. In certain situations, antipsychotic medications may be prescribed on a PRN basis. However, residents must not have PRN orders for antipsychotic medications unless the medication is necessary to treat a diagnosed specific condition and in acute or emergency situations where the symptoms have stabilized the medication should be evaluated to determine if the ongoing condition is still relevant. PRN antipsychotic medications must only be prescribed for a duration of 14-days without exception. If, after the attending physician or prescribing practitioner evaluates the resident, it is determined that ongoing need for a PRN antipsychotic medication is necessary, a new order must be provided. Note: The required evaluation includes direct examination of the resident by assessing their current condition and process and document if the antipsychotic medication is still necessary on a PRN basis, the benefit of the medication to the resident, and if the expressions or indications of distress have improved because of the medication use. A

note or report from the staff to the physician or practitioner does not constitute an evaluation.

References:

American Psychiatric Association (2016. May 1) *Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*. https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890426807.ap02

CMS (Retrieved 2025. Aug 29). Medicare State Operations Manual Appendix PP. https://www.cms.gov/files/document/appendix-pp-state-operations-manual.pdf.