

N0415: High-Risk Drug Classes: Use and Indication

N0415. High-Risk Drug Classes: Use and Indication

1. **Is taking**

Check if the resident is taking any medications by pharmacological classification, not how it is used, during the last 7 days or since admission/entry or reentry if less than 7 days

2. **Indication noted**

If Column 1 is checked, check if there is an indication noted for all medications in the drug class

	1. Is taking	2. Indication noted
	↓ Check all that apply ↓	
A. Antipsychotic	☐	☐
B. Antianxiety	☐	☐
C. Antidepressant	☐	☐
D. Hypnotic	☐	☐
E. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin)	☐	☐
F. Antibiotic	☐	☐
G. Diuretic	☐	☐
H. Opioid	☐	☐
I. Antiplatelet	☐	☐
J. Hypoglycemic (including insulin)	☐	☐
Z. None of the above	☐	

N0415: High-Risk Drug Classes: Use and Indication (cont.)**Item Rationale****Health-related Quality of Life**

- Medications are an integral part of the care provided to residents of nursing homes. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease's progress, reducing or eliminating symptoms, or preventing a disease or symptom.
- Residents taking medications in these medication categories and pharmacologic classes are at risk of side effects that can adversely affect health, safety, and quality of life.
- While assuring that only those medications required to treat the resident's assessed condition are being used, it is important to assess the need to reduce these medications wherever possible and ensure that the medication is the most effective for the resident's assessed condition.
- As part of all medication management, it is important for the interdisciplinary team to consider non-pharmacological approaches. Educating the nursing home staff and providers about non-pharmacological approaches in addition to and/or in conjunction with the use of medication may minimize the need for medications or reduce the dose and duration of those medications.

DEFINITIONS**ADVERSE
CONSEQUENCE**

An unpleasant symptom or event that is caused by or associated with a medication, impairment or decline in an individual's physical condition, mental, functional or psychosocial status. It may include various types of adverse drug reactions (ADR) and interactions (e.g., medication-medication, medication-food, and medication-disease).

**NON-
PHARMACOLOGICAL
INTERVENTION**

Approaches that do not involve the use of medication to address a medical condition.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

Planning for Care

- The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological interventions, are determined by assessing the resident's underlying condition, current signs and symptoms, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication.
- Target symptoms and goals for use of these medications should be established for each resident. Progress toward meeting the goals should be evaluated routinely.
- Possible adverse effects of these medications should be well understood by nursing staff. Educate nursing home staff to be observant for these adverse effects.
- Implement systematic monitoring of each resident taking any of these medications to identify adverse consequences early.

Steps for Assessment

1. Review the resident's medical record for documentation that any of these medications were received by the resident *and for the indication of their use* during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Review documentation from other health care settings where the resident may have received any of these medications while a resident of the nursing home (e.g., valium given in the emergency room).

Coding Instructions

- Code *all high-risk drug class* medications according to their pharmacological classification, not how they are being used.
 - **Column 1:** *Check if the resident is taking any medications by pharmacological classification during the 7-day observation period (or since admission/entry or reentry if less than 7 days).*
 - **Column 2:** *If Column 1 is checked, check if there is an indication noted for all medications in the drug class.*

DEFINITIONS

INDICATION

The identified, documented clinical rationale for administering a medication that is based upon a physician's (or prescriber's) assessment of the resident's condition and therapeutic goals.

DOSE

The total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the "daily dose."

MONITORING

The ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline and current data in order to ascertain the individual's response to treatment and care, including progress or lack of progress toward a goal. Monitoring can detect any improvements, complications, or adverse consequences of the condition or the treatments and support decisions about adding, modifying, continuing, or discontinuing any interventions.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- **N0415A 1. Antipsychotic:** *Check if* an antipsychotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415A2. Antipsychotic:** *Check if there is an indication noted for all antipsychotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415B 1. Antianxiety:** *Check if* an anxiolytic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415B2. Antianxiety:** *Check if there is an indication noted for all anxiolytic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415C 1. Antidepressant:** *Check if* an antidepressant medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415C2. Antidepressant:** *Check if there is an indication noted for all antidepressant medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415D 1. Hypnotic:** *Check if* a hypnotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415D2. Hypnotic:** *Check if there is an indication noted for all hypnotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415E 1. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin):** *Check if* an anticoagulant medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415E2. Anticoagulant:** *Check if there is an indication noted for all anticoagulant medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415F 1. Antibiotic:** *Check if* an antibiotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415F2. Antibiotic:** *Check if there is an indication noted for all antibiotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415G 1. Diuretic:** *Check if* a diuretic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- **N0415G2. Diuretic:** Check if there is an indication noted for all diuretic medications received by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415H1. Opioid:** Check if an opioid medication was *taken* by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415H2. Opioid:** Check if there is an indication noted for all opioid medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415I1. Antiplatelet:** Check if an antiplatelet medication (e.g., aspirin/extended release, dipyridamole, clopidogrel) was taken by the resident at any time during the 7-day observation period (or since admission/entry or reentry if less than 7 days).
- **N0415I2. Antiplatelet:** Check if there is an indication noted for all antiplatelet medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415J1. Hypoglycemic (including insulin):** Check if a hypoglycemic medication was taken by the resident at any time during the 7-day observation period (or since admission/entry or reentry if less than 7 days).
- **N0415J2. Hypoglycemic (including insulin):** Check if there is an indication noted for all hypoglycemic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415Z1. None of the above:** Check if none of the medications above were taken by the resident at any time during the observation period (or since admission/entry or reentry if less than 7 days).

Coding Tips and Special Populations

- Code medications in Item N0415 according to the medication's therapeutic category and/or pharmacological classification, not how it is used. For example, although oxazepam may be prescribed for use as a hypnotic, it is categorized as an antianxiety medication. Therefore, in this section, it would be coded as an antianxiety medication and not as a hypnotic.
- Medications that have more than one therapeutic category and/or pharmacological classification should be coded in **all** categories/classifications assigned to the medication, regardless of how it is being used. For example, prochlorperazine is dually classified as an antipsychotic and an antiemetic. Therefore, in this section, it would be coded as an antipsychotic, regardless of how it is used.
- Include any of these medications given to the resident by any route in any setting (e.g., at the nursing home, in a hospital emergency room) while a resident of the nursing home.
- *Do not code antiplatelet medications such as aspirin/extended release, dipyridamole, or clopidogrel as N0415E, Anticoagulant.*

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- *Anticoagulants such as Target Specific Oral Anticoagulants (TSOACs), which may or may not require laboratory monitoring, should be coded in N0415E, Anticoagulant.*
- *Do not code flushes to keep an IV access port patent.*
- *Code a medication even if it was given only once during the look-back period.*
- *Count long-acting medications, such as fluphenazine decanoate or haloperidol decanoate, that are given every few weeks or monthly **only** if they are given during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).*
- *Transdermal patches are generally worn for and release medication over a period of several days. To code N0415, only capture the medication if the transdermal patch was applied to the resident's skin during the observation period.* For example, if, during the 7-day look-back period, a fentanyl patch was applied on days 1, 4, and 7, N0415H Opioid would be *checked*, because the application occurred during the look-back period.
- *Combination medications should be coded in all categories/pharmacologic classes that constitute the combination. For example, if the resident receives a single tablet that combines an antipsychotic and an antidepressant, then **both** antipsychotic and antidepressant categories should be coded.*
- *Over-the-counter sleeping medications are not coded as hypnotics, as they are not categorized as hypnotic medications.*
- *In circumstances where reference materials vary in identifying a medication's therapeutic category and/or pharmacological classification, consult the resources/links cited in this section or consult the medication package insert, which is available through the facility's pharmacy or the manufacturer's website. *If necessary, request input from the consulting pharmacist.**
- *Herbal and alternative medicine products are considered to be dietary supplements by the Food and Drug Administration (FDA). These products are not regulated by the FDA (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). Therefore, they should not be counted as medications (e.g., melatonin, chamomile, valerian root). Keep in mind that, for clinical purposes, it is important to document a resident's intake of such herbal and alternative medicine products elsewhere in the medical record and to monitor their potential effects as they can interact with medications the resident is currently taking. For more information consult the FDA website <http://www.fda.gov/food/dietarysupplements/usingdietarysupplements/>.*
- *Opioid medications can be an effective intervention in a resident's pain management plan, but also carry risks such as overuse and constipation. A thorough assessment and root-cause analysis of the resident's pain should be conducted prior to initiation of an opioid medication and re-evaluation of the resident's pain, side effects, and medication use and plan should be ongoing.*
- *Residents who are on antidepressants should be closely monitored for worsening of depression and/or suicidal ideation/behavior, especially during initiation or change of dosage in therapy. Stopping antidepressants abruptly puts one at higher risk of suicidal ideation and behavior.*

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- When residents are having difficulty sleeping, nursing home staff should explore non-pharmacological interventions (e.g., sleep hygiene approaches that individualize the sleep and wake times to accommodate the person's wishes and prior customary routine) to try to improve sleep prior to initiating pharmacologic interventions. If residents are currently on sleep-enhancing medications, nursing home staff can try non-pharmacologic interventions to help reduce the need for these medications or eliminate them.
- Many psychoactive medications increase confusion, sedation, and falls. For those residents who are already at risk for these conditions, nursing home staff should develop plans of care that address these risks.
- Doses of psychoactive medications differ in acute and long-term treatment. Doses should always be the lowest possible to achieve the desired therapeutic effects and be deemed necessary to maintain or improve the resident's function, well-being, safety, and quality of life. Duration of treatment should also be in accordance with pertinent literature, including clinical practice guidelines.
- Since medication issues continue to evolve and new medications are being approved regularly, it is important to refer to a current authoritative source for detailed medication information, such as indications and precautions, dosage, monitoring, or adverse consequences.
- Anticoagulants must be monitored with dosage frequency determined by clinical circumstances and duration of use. Certain anticoagulants require monitoring via laboratory results (e.g., Prothrombin Time [PT]/International Normalization Ratio [INR]).
 - Multiple medication interactions exist with use of anticoagulants (information on common medication-medication interactions can be found in the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html>]), which may
 - significantly increase PT/INR results to levels associated with life-threatening bleeding, or
 - decrease PT/INR results to ineffective levels, or increase or decrease the serum concentration of the interacting medication.

DEFINITION

SLEEP HYGIENE

Practices, habits and environmental factors that promote and/or improve sleep patterns.

DEFINITION

MEDICATION INTERACTION

The impact of medication or other substance (such as nutritional supplements including herbal products, food, or substances used in diagnostic studies) upon another medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

Example

1. The Medication Administration Record for *Resident P* reflects the following *during the 7-day observation period*:

- Risperidone 0.5 mg PO BID PRN: Received once a day on Monday, Wednesday, and Thursday *for bipolar disorder*.
- Lorazepam 1 mg PO QAM: Received every day *for bipolar disorder*.
- Temazepam 15 mg PO QHS PRN: Received at bedtime on Tuesday and Wednesday only.

Coding: Medications in N0415, would be coded as follows: **N0415A1 and N0415A2. Antipsychotic = checked;** risperidone is an antipsychotic medication *and indication of use for bipolar disorder noted*. **N0415B1 and N0415B2. Antianxiety = checked;** lorazepam is an antianxiety medication *and indication of use for bipolar disorder noted*. **N0415D1. Hypnotic = checked;** temazepam is a hypnotic medication. **N0415D2. Hypnotic = not checked;** *indication for use of temazepam was not noted*.

Please note: if a resident is receiving medications in all three *of these high-risk drug classes* simultaneously there must be a clear clinical indication for the use of these medications. Administration of these types of medications, particularly in this combination, could be interpreted as chemically restraining the resident. Adequate documentation is essential in justifying their use.

Additional information on psychoactive medications can be found in the **Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)** (or subsequent editions) (<https://www.psychiatry.org/psychiatrists/practice/dsm>), and the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html>)].

The following resources and tools provide information on medications including classifications, warnings, appropriate dosing, drug interactions, and medication safety information.

- GlobalRPh Drug Reference, <http://globalrph.com/drug-A.htm>
- USP Pharmacological Classification of Drugs, <http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40#Guidelines6>. *Directions:* Scroll to the bottom of this webpage and click on the pdf download for “USP Medicare Model Guidelines (With Example Part D Drugs)”
- Medline Plus, <https://www.nlm.nih.gov/medlineplus/druginformation.html>

N0415: *High-Risk Drug Classes: Use and Indication* (cont.)

The above resource list is not all-inclusive, and use of these resources is not required for MDS completion. The resources are being provided as a convenience, for informational purposes only, and CMS is not responsible for their accessibility, content, or accuracy. Providers are responsible for coding each medication's pharmacological/therapeutic classification accurately. Caution should be exercised when using lists of medication categories, and providers should always refer to the details concerning each medication when determining its medication classification.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.