

Regulatory Update: Compliance Cue

Guidance for MDS Updates 10.1.2023



MDS 3.0 Changes: Section N

Section N of the MDS 3.0 will demonstrate significant changes effective October 1, 2023. Specifically, **Section N0410 (Medications Received)** will be removed and replaced with **Section N0415 (High-Risk Drug Classes: Use and Indication)**.



Why the Change?

Updating the MDS 3.0 Section N to highlight these select drug classes emphasizes high-risk medications for more thorough review and evaluation. CMS identifies these drug categories and pharmacologic classes as high risk based on their profound potential to adversely affect health, safety, and quality of life, behooving staff to ensure they are warranted with documented indications.



Show me

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	<input type="checkbox"/>	<input type="checkbox"/>
B. Antianxiety	<input type="checkbox"/>	<input type="checkbox"/>
C. Antidepressant	<input type="checkbox"/>	<input type="checkbox"/>
D. Hypnotic	<input type="checkbox"/>	<input type="checkbox"/>
E. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin)	<input type="checkbox"/>	<input type="checkbox"/>
F. Antibiotic	<input type="checkbox"/>	<input type="checkbox"/>
G. Diuretic	<input type="checkbox"/>	<input type="checkbox"/>
H. Opioid	<input type="checkbox"/>	<input type="checkbox"/>
I. Antiplatelet	<input type="checkbox"/>	<input type="checkbox"/>
J. Hypoglycemic (including insulin)	<input type="checkbox"/>	<input type="checkbox"/>
Z. None of the above	<input type="checkbox"/>	<input type="checkbox"/>

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How to Proceed

Effective 10.1.2023, MDS coordinators are to review for documentation that **any high-risk drugs were received by the resident and for the indication of their use.**

Inspect for high-risk drugs and respective indications by examining the resident's medical record and documentation from other healthcare settings where they may have received such medications (e.g., emergency

department visits), during the 7-day look-back period (or since admission/entry/reentry if less than 7 days have elapsed at the time of assessment).

Use Section N to indicate if the resident is taking any high-risk drugs, by checking the appropriate box in column 1, corresponding to their pharmacologic classification(s).

If no high-risk drugs are identified across the 7-day assessment period, check the box "Z. None of the above."

If any column 1 box other than "Z" is checked, evaluate if there is an indication noted for all medications within the designated drug class(es) and denote findings by checking the corresponding box in column 2.



Coding Tips

- Code medications according to their therapeutic category and/or pharmacological classification, not how they are used. For example, oxazepam prescribed for use as a hypnotic would still be coded as an anti-anxiety medication per its drug class.
- A drug with ≥ 1 therapeutic category and/or pharmacological classification should be coded in all categories/classifications assigned to it, regardless of use. 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 use).
- Code a medication even if it was given only once during the look-back observation period.
- Include any high-risk medications given to the individual, while a resident of the nursing home during the observation period, regardless of route (e.g., PO, IM, or IV) or setting (e.g., at the nursing home, in a hospital emergency room).
- 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.
- 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.
- 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.
- OTC sleeping medications are not categorized as hypnotics and do not need to be coded as such.
- Herbal and alternative medicine products (e.g., melatonin, chamomile, valerian root) are considered to be dietary supplements by the FDA and, therefore, not regulated like medications (i.e., do not need to be coded in N0415).
- Do not code antiplatelet medications such as aspirin/extended release, dipyridamole, or clopidogrel as N0415E, Anticoagulant.
- In circumstances where reference materials vary in identifying a medication's therapeutic category and/or pharmacological classification, consult the resources/links cited in the MDS 3.0 RAI manual or consult the medication package insert.

- [GlobalRPh Drug Reference](#)
- [USP Pharmacological Classification of Drugs](#)
- [Medline Plus](#)

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Example

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 M, W, and Th for bipolar disorder.

Lorazepam 1 mg PO QAM: Received every day for bipolar disorder.

Temazepam 15 mg PO QHS PRN: Received at bedtime on T and W 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 was not noted.



Q&As

Q: Can you clarify what is considered a medication's indication?

A: CMS considers the indication to be defined as the identified, documented clinical rationale for administering a medication that is based upon the prescriber's assessment of the resident's condition and therapeutic goals.

Q: If a resident is taking two antipsychotic medications but there is only an indication noted for one, should Column 2 (Indication noted) be checked?

A: CMS states, "Per the scenario, you would not check Column 2 (Indication noted), as there is not an indication noted for all antipsychotic medications taken by the resident at any time during the observation period."

Q: Regarding N0415, should MDS coordinators include anticoagulants used to flush an IV line?

A: CMS states, "Do not include flushes to keep an IV access port patent when coding N0415E. This will be added as a coding tip to the final version of the MDS RAI 3.0 v1.18.11 User's Manual."



Potential Effects

MDS Section N will impact the Nursing Home Quality Indicators (NHQI) program with the inclusion of the indication of use parameter. Beyond quality components, the section updates open nursing homes up to survey issues if medications are continued without a valid indication (i.e., not supported by documentation to back up assessment).

Additional Resources

[MDS 3.0 Item Set \(cms.gov\)](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Spotlight)

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An abridged list of example high-risk medications for each category is included on the following pages

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High-Risk Drugs

This abridged table summarizes medications classified as high-risk drugs per the categories defined by MDS Section N. They are arranged alphabetically, by generic name. These lists are not intended to be exhaustive or all-inclusive, but rather, serve as a quick-reference guide for staff education.

Antipsychotic	Antianxiety	Antidepressant	Hypnotic	Anticoagulant
Aripiprazole	Alprazolam	Amitriptyline	Daridorexant	Apixaban
Asenapine	Buspirone	Amoxapine	Estazolam	Argatroban
Brexipiprazole	Chlordiazepoxide	Brexanolone	Eszopiclone	Bivalirudin
Cariprazine	Clonazepam	Bupropion	Lemborexant	Dabigatran
Chlorpromazine	Clorazepate	Citalopram	Quazepam	Dalteparin
Clozapine	Diazepam	Clomipramine	Ramelteon	Edoxaban
Droperidol	Lorazepam	Desipramine	Suvorexant	Enoxaparin
Fluphenazine	Meprobamate	Desvenlafaxine	Tasimelteon	Fondaparinux
Haloperidol	Oxazepam	Doxepin	Temazepam	Heparin
Iloperidone		Duloxetine	Zaleplon	Rivaroxaban
Loxapine		Escitalopram	Zolpidem	Warfarin
Lurasidone		Esketamine	Zopiclone	
Molindone		Fluoxetine	Flurazepam	
Olanzapine		Fluvoxamine		
Olanzapine & Samidorphan		Imipramine		
Paliperidone		Isocarboxazid		
Perphenazine		Levomilnacipran		
Pimavanserin		Mirtazapine		
Pimozide		Nefazodone		
Prochlorperazine		Nortriptyline		
Quetiapine		Paroxetine		
Risperidone		Phenelzine		
Thioridazine		Protriptyline		
Thiothixene		Selegiline		
Trifluoperazine		Sertraline		
Ziprasidone		Tranlycypromine		
		Trazodone		
		Trimipramine		
		Venlafaxine		
		Vilazodone		
		Vortioxetine		

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High-Risk Drugs (Continued)

Antibiotic	Diuretic	Opioid	Antiplatelet	Hypoglycemic
Amoxicillin	Acetazolamide	Buprenorphine	Anagrelide	Acarbose
Ampicillin	Amiloride	Butorphanol	Aspirin	Alogliptin
Azithromycin	Bumetanide	Codeine	Cangrelor	Canagliflozin
Cefadroxil	Chlorothiazide	Fentanyl	Cilostazol	Dapagliflozin
Cefazolin	Chlorthalidone	Hydrocodone	Clopidogrel	Dulaglutide
Cefdinir	Eplerenone	Hydromorphone	Dipyridamole	Empagliflozin
Cefepime	Ethacrynic Acid	Levorphanol	Eptifibatide	Ertugliflozin
Cefpodoxime	Furosemide	Meperidine	Prasugrel	Exenatide
Ceftazidime	Hydrochlorothiazide	Methadone	Ticagrelor	Glimepiride
Ceftriaxone	Indapamide	Morphine	Tirofiban	Glipizide
Cefuroxime	Methazolamide	Nalbuphine	Vorapaxar	Glyburide
Cephalexin	Metolazone	Oxycodone		Insulins (Aspart, Degludec, Detemir, Glargine, Glulisine, Lispro, NPH, Regular)
Ciprofloxacin	Spirolactone	Oxymorphone		Linagliptin
Clindamycin	Torsemide	Sufentanil		Liraglutide
Daptomycin	Triamterene	Tapentadol		Lixisenatide
Doxycycline		Tramadol		Metformin
Ertapenem				Miglitol
Fosfomycin				Nateglinide
Gentamicin				Pioglitazone
Levofloxacin				Repaglinide
Linezolid				Saxagliptin
Meropenem				Semaglutide
Methenamine				Sitagliptin
Minocycline				Tirzepatide
Nitrofurantoin				
Penicillin				
Piperacillin				
Rifaximin				
Trimethoprim				
Vancomycin				