**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0022

**Measure Title**: Use of High-Risk Medications in Older Adults

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** N/A

**Date of Submission**: Click here to enter a date

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Prescribing of potentially harmful drugs for older adults

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

2020 Submission

Older adults at risk of adverse drug events >> clinician judiciously prescribes potentially harmful medications, selecting alternative pharmacologic and non-pharmacologic treatment approaches when possible >> adverse drug events are avoided >> morbidity and mortality is reduced

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

N/A

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2020 Submission  American Geriatrics Society 2019 Beers Criteria Update Expert Panel. 2019. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of the American Geriatrics Society, 67(4): 674-94.  Below are the guiding principles that were developed to determine which medications would be included in the measure.  **Guiding Principles**   1. Include only medications listed in Table 2: 2019 AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. 2. Include only prescription medications. 3. Include only medications where the AGS Recommendation indicates “avoid” and that can be identified reliably from prescription drug claims data. 4. Include only medications where the AGS Recommendation or Rationale includes caveats (“except in”) that can be identified reliably from administrative claims data. 5. Do not include medications that are rarely prescribed and would not provide a sufficient denominator count for quality measurement. 6. If including a medication in the measure would likely result in the increased use of another potentially harmful medication that is not included in the measure, an exception to these guiding principles may be warranted to reduce this unintended consequence.   2016 Submission  American Geriatrics Society 2015 Beers Criteria Update Expert Panel. 2015. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of the American Geriatrics Society, 63(11): 2227-2246. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2020 Submission  Language in the table below is taken verbatim from Table 2 (pages 5-9) of the *American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. The following changes to the 2019 Beers Criteria were applied to the DAE measure during the most recent update:   * Added *Pyrilamine* to the list of anticholinergics, first-generation antihistamines * Added *Methscopolamine* to the list of antispasmodics * Removed *Ticlopidine* from the list of antithrombotics * Added *Glimepiride* to the list of endocrine system, sulfonylureas, long-duration * Removed *Pentazocine* from the list of pain medications, other  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Organ System,  Therapeutic  Category, Drugs | Rationale | Recommendation | Quality of Evidence | Strength of Recommendation | | Anticholinergics: First-generation antihistamines (p. 5)  Brompheniramine  Carbinoxamine  Chlorpheniramine  Clemastine  Cyproheptadine  Dexbrompheniramine  Dexchlorpheniramine  Dimenhydrinate  Diphenhydramine (oral)  Doxylamine  Hydroxyzine  Meclizine  Promethazine  Pyrilamine  Triprolidine | Highly anticholinergic; clearance reduced with  advanced age, and tolerance develops when used as hypnotic; risk of confusion, dry mouth, constipation, and other anticholinergic effects or  toxicity  Use of diphenhydramine in situations such as  acute treatment of severe allergic reaction may  be appropriate | Avoid | Moderate | Strong | | Antiparkinsonian agents (p. 5)  Benztropine (oral)  Trihexyphenidyl | Not recommended for prevention or treatment of extrapyramidal symptoms with antipsychotics; more-effective agents available for treatment of  Parkinson disease | Avoid | Moderate | Strong | | Antispasmodics (p. 5)  Atropine (excludes ophthalmic)  Belladonna alkaloids  Clidinium-Chlordiazepoxide  Dicyclomine Homatropine (excludes ophthalmic)  Hyoscyamine  Methscopolamine  Propantheline  Scopolamine | Highly anticholinergic, uncertain effectiveness | Avoid | Moderate | Strong | | Antithrombotics (p. 5)  Dipyridamole, oral short-acting (does not apply to the extended release combination with aspirin) | May cause orthostatic hypotension; more effective alternatives available; intravenous form acceptable for use in cardiac stress testing | Avoid | Moderate | Strong | | Anti-infective (p. 5)  Nitrofurantoin | Potential for pulmonary toxicity, hepatoxicity, and peripheral neuropathy, especially with long-term use; safer alternatives available | Avoid in individuals with creatinine  clearance <30 mL/min or for long-term  suppression of bacteria | Low | Strong | | Cardiovascular (p.5)  Peripheral alpha-1 blockers for treatment of hypertension  Doxazosin  Prazosin  Terazosin | High risk of orthostatic hypotension and associated harms, especially in older adults; not recommended as routine treatment for hypertension; alternative agents have superior risk/benefit profile | Avoid use as an antihypertensive | Moderate | Strong | | Cardiovascular (p.6)  Central alpha-agonists  Clonidine for first-line treatment of hypertension  Other CNS alpha-agonists  Guanabenz  Guanfacine  Methyldopa  Reserpine (>0.1 mg/d) | High risk of adverse CNS effects; may cause bradycardia and orthostatic hypotension; not  recommended as routine treatment for hypertension | Avoid as first-line antihypertensive  Avoid other CNS alpha-agonists as listed | Low | Strong | | Cardiovascular (p.6)  Disopyramide | May induce heart failure in older adults because of potent negative inotropic action; strongly anticholinergic; other antiarrhythmic drugs preferred | Avoid | Low | Strong | | Cardiovascular (p.6)  Dronodarone | Worse outcomes have been reported in patients taking dronedarone who have permanent atrial fibrillation or severe or recently decompensated heart failure. | Avoid in individuals with permanent atrial fibrillation or severe or recently decompensated heart failure | High | Strong | | Cardiovascular (p.6)  Digoxin for first-line treatment of atrial fibrillation or of heart failure | Use in atrial fibrillation: should not be used as a first-line agent in atrial fibrillation, because there are safer and more effective alternatives for rate control supported by high-quality evidence.  Use in heart failure: evidence for benefits and harms of digoxin is conflicting and of lower quality; most but not all of the evidence concerns use in HFrEF. There is strong evidence for other agents as first-line therapy to reduce hospitalizations and mortality in adults with HFrEF.  in heart failure, higher dosages not associated with additional benefit and may  increase risk of toxicity  Decreased renal clearance of digoxin may lead to increased risk of toxic effects; further dose  reduction may be necessary in patients with Stage 4 or 5 chronic kidney disease | Avoid this rate control agent as first-line therapy for atrial fibrillation  Avoid as first-line therapy for heart failure  If used for atrial fibrillation or heart failure, avoid dosages >0.125 mg/day | Atrial fibrillation: Low  Heart failure: Low  Dosage >0.125 mg/d: Moderate | Atrial fibrillation: Strong  Heart failure: Strong  Dosage >0.125 mg/d:  Strong | | Cardiovascular (p.6)  Nifedipine, immediate  release | Potential for hypotension; risk of precipitating myocardial ischemia | Avoid | High | Strong | | Cardiovascular (p.6)  Amiodarone | Effective for maintaining sinus rhythm but has greater toxicities than other antiarrhythmics used in atrial fibrillation; may be reasonable first-line therapy in patients with concomitant heart failure or substantial left ventricular hypertrophy if rhythm control is preferred overrate control | Avoid as first-line therapy for atrial fibrillation unless patient has heart failure or substantial left ventricular hypertrophy | High | Strong | | Central Nervous System (p. 6)  Antidepressants, alone or in  combination  Amitriptyline  Amoxapine  Clomipramine  Desipramine  Doxepin >6 mg/d  Imipramine  Nortriptyline  Paroxetine  Protriptyline  Trimipramine | Highly anticholinergic, sedating, and cause orthostatic hypotension; safety profile of low dose doxepin (≤6 mg/d) comparable with that of placebo | Avoid | High | Strong | | Central Nervous System (p. 7)  Antipsychotics, first (conventional) and second (atypical) generation | Increased risk of cerebrovascular accident (stroke) and greater rate of cognitive decline and mortality in persons with dementia  Avoid antipsychotics for behavioral problems of dementia or delirium unless nonpharmacological options (eg, behavioral interventions) have failed or are not possible and the older adult is threatening substantial harm to self or others | Avoid, except in schizophrenia or bipolar disorder, or for short-term use as antiemetic during chemotherapy | Moderate | Strong | | Central Nervous System (p. 7)  Barbiturates  Amobarbital  Butabarbital  Butalbital  Mephobarbital  Pentobarbital  Phenobarbital  Secobarbital | High rate of physical dependence, tolerance to sleep benefits, greater risk of overdose at low  dosages | Avoid | High | Strong | | Central Nervous System (p. 7)  Benzodiazepines  Short and immediate acting:  Alprazolam  Estazolam  Lorazepam  Oxazepam  Temazepam  Triazolam  Long acting:  Chlordiazepoxide (alone or in combination with amitriptyline or clidinium)  Clonazepam  Clorazepate  Diazepam  Flurazepam  Quazepam | Older adults have increased sensitivity to benzodiazepines and decreased metabolism of long-acting agents; in general, all benzodiazepines increase risk of cognitive impairment, delirium, falls, fractures, and motor vehicle crashes in older adults  May be appropriate for seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, severe generalized anxiety disorder, and periprocedural anesthesia | Avoid | Moderate | Strong | | Central Nervous System (p. 7)  Meprobamate | High rate of physical dependence; very sedating | Avoid | Moderate | Strong | | Central Nervous System (p. 7)  Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics (ie, “Z-drugs”)  Eszopiclone  Zolpidem  Zaleplon | Nonbenzodiazepine benzodiazepine receptor agonist hypnotics (ie, Z drugs) have adverse events similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures); increased emergency department visits and hospitalizations; motor vehicle crashes; minimal improvement in sleep latency and duration | Avoid | Moderate | Strong | | Central Nervous System (p. 7)  Ergoloid mesylates (dehydrogenated ergot alkaloids)  Isoxsuprine | Lack of efficacy | Avoid | High | Strong | | Endocrine (p. 8)  Androgens  Methyltestosterone  Testosterone | Potential for cardiac problems; contraindicated in men with prostate cancer | Avoid unless indicated for confirmed hypogonadism with clinical symptoms | Moderate | Weak | | Endocrine (p. 8)  Desiccated thyroid | Concerns about cardiac effects; safer  alternatives available | Avoid | Low | Strong | | Endocrine (p. 8)  Estrogens with or without  progestins | Evidence of carcinogenic potential (breast and endometrium); lack of cardioprotective effect and cognitive protection in older women. Evidence indicates that vaginal estrogens for the treatment of vaginal dryness are safe and effective; women with a history of breast cancer who do not respond to nonhormonal therapies are advised to discuss the risk and benefits of low-dose vaginal estrogen (dosages of estradiol <25 lg twice weekly) with their healthcare provider | Avoid systemic estrogen (e.g., oral and topical patch)  Vaginal cream or tablets: acceptable to  use low-dose intravaginal estrogen for  management of dyspareunia, recurrent lower urinary tract infections, and other vaginal  symptoms | Oral and patch: High  Vaginal cream or tablets:  Moderate | Oral and patch: Strong  Topical vaginal cream or tablets: Weak | | Endocrine (p. 8)  Growth hormone | Impact on body composition is small and associated with edema, arthralgia, carpal tunnel syndrome, gynecomastia, impaired fasting glucose | Avoid, except for patients rigorously diagnosed by evidence-based criteria with growth hormone deficiency due to an established etiology | High | Strong | | Endocrine (p. 8)  Insulin, sliding scale (insulin regimens containing only short- or rapid-acting insulin dosed according to current blood glucose levels without concurrent use of basal or long-acting insulin) | Higher risk of hypoglycemia without improvement in hyperglycemia management regardless of care setting. Avoid insulin regimens that include only short- or rapid-acting insulin dosed according to current blood glucose levels without concurrent use of basal or long-acting insulin. This recommendation does not apply to regimens that contain basal insulin or long-acting insulin. | Avoid | Moderate | Strong | | Endocrine (p. 8)  Megestrol | Minimal effect on weight; increases risk of thrombotic events and possibly death in older  adults | Avoid | Moderate | Strong | | Endocrine (p. 8)  Sulfonylureas, long-duration  Chlorpropamide  Glimepiride  Glyburide (also known as glibenclamide) | Chlorpropamide: prolonged half-life in older adults; can cause prolonged hypoglycemia; causes syndrome of inappropriate antidiuretic hormone secretion  Glyburide: higher risk of severe prolonged hypoglycemia in older adults | Avoid | High | Strong | | Gastrointestinal (p. 8)  Metoclopramide | Can cause extrapyramidal effects, including tardive dyskinesia; risk may be greater in frail older adults and with prolonged exposure | Avoid, unless for gastroparesis with duration of use not to exceed 12 weeks except in rare cases | Moderate | Strong | | Gastrointestinal (p. 8)  Mineral oil, given orally | Potential for aspiration and adverse effects; safer alternatives available | Avoid | Moderate | Strong | | Gastrointestinal (p. 8)  Proton-pump inhibitors | Risk of *Clostridium difficile* infection and bone loss and fractures | Avoid scheduled use for >8 weeks unless for high-risk patients (eg, oral corticosteroids or chronic NSAID use), erosive esophagitis, Barrett esophagitis, pathological hypersecretory condition, or demonstrated need for maintenance treatment (eg, because of failure of drug discontinuation trial or H2-receptorantagonists) | High | Strong | | Pain medications (p. 9)  Meperidine | Not effective oral analgesic in dosages commonly used; may have higher risk of neurotoxicity, including delirium, than other  opioids; safer alternatives available | Avoid | Moderate | Strong | | Pain medications (p. 9)  Non-cyclooxygenase-selective  NSAIDs, oral:  Aspirin >325 mg/day  Diclofenac  Diflunisal  Etodolac  Feneprofen  Ibuprofen  Ketoprofen  Meclofenamate  Mefenamic acid  Meloxicam  Nabumetone  Naproxen  Oxaprozin  Piroxicam  Sulindac  Tolmetin | Increased risk of gastrointestinal bleeding or peptic ulcer disease in high-risk groups, including those >75 years or taking oral or parenteral corticosteroids, anticoagulants, or antiplatelet agents; use of proton-pump inhibitor or misoprostol reduces but does not eliminate risk. Upper gastrointestinal ulcers, gross bleeding, or perforation caused by NSAIDs occur in ~1% of patients treated for3-6 months and in ~2%-4% of patients treated for 1 year; these trends continue with longer duration of use. Also can increase blood pressure and induce kidney injury. Risks are dose related. | Avoid chronic use, unless other alternatives are not effective and patient can take gastroprotective agent (proton-pump inhibitor or misoprostol) | Moderate | Strong | | Pain medications (p. 9)  Indomethacin  Ketorolac, includes parenteral | Indomethacin is more likely than other NSAIDs to have adverse CNS effects. Of all the NSAIDs,  indomethacin has the most adverse effects. Increased risk of gastrointestinal bleeding, peptic ulcer disease, and acute kidney injury in older adults | Avoid | Moderate | Strong | | Pain medications (p. 9)  Skeletal muscle relaxants  Carisoprodol  Chlorzoxazone  Cyclobenzaprine  Metaxalone  Methocarbamol  Orphenadrine | Most muscle relaxants poorly tolerated by older adults because some have anticholinergic adverse effects, sedation, increased risk of fractures; effectiveness at dosages tolerated by older adults questionable | Avoid | Moderate | Strong | | Genitourinary (p. 9)  Desmopressin | High risk of hyponatremia; safer alternative treatments | Avoid for treatment of nocturia or nocturnal polyuria | Moderate | Strong |   **2016 Submission**  Language in the table below is taken verbatim from Table 2 (pages 5-10) of the *American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. Evidence tables containing summaries of each study supporting the recommendations can be found on the American Geriatrics Society’s website: <http://www.americangeriatrics.org/>.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Organ System,  Therapeutic  Category, Drugs | Rationale | Recommendation | Quality of Evidence | Strength of Recommendation | | Anticholinergics: First-generation antihistamines (p. 5)  Brompheniramine  Carbinoxamine  Chlorpheniramine  Clemastine  Cyproheptadine  Dexbrompheniramine  Dexchlorpheniramine  Dimenhydrinate  Diphenhydramine (oral)  Doxylamine  Hydroxyzine  Meclizine  Promethazine  Triprolidine | Highly anticholinergic; clearance reduced with  advanced age, and tolerance develops when used as hypnotic; risk of confusion, dry mouth, constipation, and other anticholinergic effects or  toxicity  Use of diphenhydramine in situations such as  acute treatment of severe allergic reaction may  be appropriate | Avoid | Moderate | Strong | | Antiparkinsonian agents (p. 5)  Benztropine (oral)  Trihexyphenidyl | Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more-effective agents available for treatment of  Parkinson disease | Avoid | Moderate | Strong | | Antispasmodics (p. 5)  Atropine (excludes ophthalmic)  Belladonna alkaloids  Clidinium-Chlordiazepoxide  Dicyclomine  Hyoscyamine  Propantheline  Scopolamine | Highly anticholinergic, uncertain effectiveness | Avoid | Moderate | Strong | | Antithrombotics (p. 5)  Dipyridamole, oral short-acting (does not apply to the extended release combination with aspirin) | May cause orthostatic hypotension; more effective alternatives available; intravenous form acceptable for use in cardiac stress testing | Avoid | Moderate | Strong | | Antithrombotics (p. 5)  Ticlopidine | Safer, effective alternatives available | Avoid | Moderate | Strong | | Anti-infective (p. 5)  Nitrofurantoin | Potential for pulmonary toxicity, hepatoxicity, and peripheral neuropathy, especially with long-term use; safer alternatives available | Avoid in individuals with creatinine  clearance <30 mL/min or for long-term  suppression of bacteria | Low | Strong | | Central alpha blockers (p. 6)  Guanabenz  Guanfacine  Methyldopa  Reserpine (>0.1 mg/d) | High risk of adverse CNS effects; may cause bradycardia and orthostatic hypotension; not  recommended as routine treatment for hypertension | Avoid | Low | Strong | | Central alpha blockers (p. 6)  Disopyramide | Disopyramide is a potent negative inotrope and therefore may induce heart failure in older adults; strongly anticholinergic; other  antiarrhythmic drugs preferred | Avoid | Low | Strong | | Central alpha blockers (p. 6)  Digoxin | Use in atrial fibrillation: should not be used as a first-line agent in atrial fibrillation, because more effective alternatives exist and it may be associated with increased mortality  Use in heart failure: questionable effects on risk of hospitalization and may be associated with  increased mortality in older adults with heart failure; in heart failure, higher dosages not associated with additional benefit and may  increase risk of toxicity  Decreased renal clearance of digoxin may lead to increased risk of toxic effects; further dose  reduction may be necessary in patients with Stage 4 or 5 chronic kidney disease | If used for atrial fibrillation or heart failure, avoid dosages >0.125 mg/d | Dosage >0.125 mg/d: Moderate | Dosage >0.125 mg/d:  Strong | | Central alpha blockers (p. 6)  Nifedipine, immediate  release | Potential for hypotension; risk of precipitating myocardial ischemia | Avoid | High | Strong | | Central Nervous System (p. 7)  Antidepressants, alone or in  combination  Amitriptyline  Amoxapine  Clomipramine  Desipramine  Doxepin >6 mg/d  Imipramine  Nortriptyline  Paroxetine  Protriptyline  Trimipramine | Highly anticholinergic, sedating, and cause orthostatic hypotension; safety profile of low dose doxepin (≤6 mg/d) comparable with that of placebo | Avoid | High | Strong | | Central Nervous System (p. 7)  Barbiturates  Amobarbital  Butabarbital  Butalbital  Mephobarbital  Pentobarbital  Phenobarbital  Secobarbital | High rate of physical dependence, tolerance to sleep benefits, greater risk of overdose at low  dosages | Avoid | High | Strong | | Central Nervous System (p. 8)  Meprobamate | High rate of physical dependence; very sedating | Avoid | Moderate | Strong | | Central Nervous System (p. 8)  Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics  Eszopiclone  Zolpidem  Zaleplon | Benzodiazepine-receptor agonists have adverse events similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures); increased emergency department visits and hospitalizations; motor vehicle crashes; minimal improvement in sleep latency and duration | Avoid | Moderate | Strong | | Central Nervous System (p. 8)  Ergoloid mesylates (dehydrogenated ergot alkaloids)  Isoxsuprine | Lack of efficacy | Avoid | High | Strong | | Endocrine (p. 8)  Desiccated thyroid | Concerns about cardiac effects; safer  alternatives available | Avoid | Low | Strong | | Endocrine (p. 8)  Estrogens with or without  progestins | Evidence of carcinogenic potential (breast and endometrium); lack of cardioprotective effect and cognitive protection in older women. Evidence indicates that vaginal estrogens for the treatment of vaginal dryness are safe and effective; women with a history of breast cancer who do not respond to nonhormonal therapies are advised to discuss the risk and benefits of low-dose vaginal estrogen (dosages of estradiol <25 lg twice weekly) with their healthcare provider | Avoid oral and topical patch  Vaginal cream or tablets: acceptable to  use low-dose intravaginal estrogen for  management of dyspareunia, lower urinary tract infections, and other vaginal  symptoms | Oral and patch: High  Vaginal cream or tablets:  Moderate | Oral and patch: Strong  Topical vaginal cream or tablets: Weak | | Endocrine (p. 9)  Megestrol | Minimal effect on weight; increases risk of thrombotic events and possibly death in older  adults | Avoid | Moderate | Strong | | Endocrine (p. 9)  Sulfonylureas, long-duration  Chlorpropamide  Glyburide | Chlorpropamide: prolonged half-life in older adults; can cause prolonged hypoglycemia; causes syndrome of inappropriate antidiuretic hormone secretion  Glyburide: higher risk of severe prolonged hypoglycemia in older adults | Avoid | High | Strong | | Pain medications (p. 9)  Meperidine | Not effective oral analgesic in dosages commonly used; may have higher risk of neurotoxicity, including delirium, than other  opioids; safer alternatives available | Avoid, especially in individuals with  chronic kidney disease | Moderate | Strong | | Pain medications (p. 10)  Non-cyclooxygenase-selective  NSAIDs, oral:  Indomethacin  Ketorolac, includes parenteral | Indomethacin is more likely than other NSAIDs to have adverse CNS effects. Of all the NSAIDs,  indomethacin has the most adverse effects. Increased risk of gastrointestinal bleeding, peptic ulcer disease, and acute kidney injury in older adults | Avoid | Moderate | Strong | | Pain medications (p. 10)  Pentazocine | Opioid analgesic that causes CNS adverse effects, including confusion and hallucinations,  more commonly than other opioid analgesic drugs; is also a mixed agonist and antagonist; safer alternatives available | Avoid | Low | Strong | | Pain medications (p. 10)  Skeletal muscle relaxants  Carisoprodol  Chlorzoxazone  Cyclobenzaprine  Metaxalone  Methocarbamol  Orphenadrine | Most muscle relaxants poorly tolerated by older adults because some have anticholinergic adverse effects, sedation, increased risk of fractures; effectiveness at dosages tolerated by older adults questionable | Avoid | Moderate | Strong | |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2020 Submission  See the table above for the grade assigned to the evidence for each medication class. The chart below is excerpted from the 2019 Beers Criteria article and contains the definitions for the quality of evidence ratings and the strength of recommendations.   |  |  |  | | --- | --- | --- | | **Table 1. Designations of Quality of Evidence and Strength of Recommendations\*** | | | | **Quality of Evidence** | | | | *Quality of evidence ratings for each criterion are based on synthetic assessment of two complementary approaches to evaluating the quality of evidence.* | | | | ACP-based approach | | GRADE-based approach | | High-quality evidence | “Evidence…obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change our confidence in the estimate of effect.” | Consider the following five factors for the studies that comprise the best-available evidence for a given criterion:  1. Risk of bias: Severity of threats to studies’ internal validity (eg, randomized vs observational design, potential for confounding, bias in measurement)  2. Inconsistency: Do different studies provide similar or different estimates of effect size  3. Indirectness: How relevant are the studies to the clinical question at hand (eg, nature of study of population, comparison group, type of outcomes measured)  4. Imprecision: Precision of estimates of effect  5. Publication bias: Risk of bias due to selective publication of results | | Moderate-quality evidence | “Evidence…obtained from RCTs with important limitations…. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on our confidence in the estimate of effect and may change the estimate.” | | Low-quality evidence | “Evidence obtained from observational studies would typically be rated as low quality because of the risk for bias. Low-quality evidence means that further research is very likely to have an important effect on our confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies.” | | ↓↓↓↓↓ | | | | Overall quality of evidence that supports a given criterion: high, moderate, low | | | | **Strength of Evidence** | | | | *Strength of evidence ratings for each criterion are based on synthetic integration of the quality of evidence, the frequency and severity of potential adverse events and relationship to potential benefits, and clinical judgment.* | | | | Strong | Harms, adverse events, and risks clearly outweigh benefits. | | | Weak | Harms, adverse events, and risks may not outweigh benefits. | |   Abbreviations: ACP, American College of Physicians; GRADE, Grading of Recommendations Assessment, Development and Evaluation.  \*Adapted from:  Qaseem A, Snow V, Owens DK, et al. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. Ann Intern Med. 2010;153:194–199.  Guyatt G, Oxman AD, Sultan S, et al. GRADE guidelines: 11. Making an overall rating of confidence in effect estimates for a single outcome and for all outcomes. J Clin Epidemiol. 2013;66(2):151–157.  Andrews JC, Schünemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation’s direction and strength. J Clin Epidemiol. 2013;66(7):726–735.  2016 Submission  The American Geriatrics Society 2015 Beers Criteria Update Expert Panel used the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) rating process to rate the quality of evidence. Each panelist independently rated the quality of evidence and strength of recommendation for each criterion using the American College of Physicians’ Guideline Grading System (Qaseem et al., 2010), which is based on the GRADE scheme (The GRADE Working Group). The chart below is excerpted from the Beers Criteria article and contains the definitions for the quality of evidence ratings and the strength of recommendations.    References:  Qaseem A, Snow V, Owens DK et al. The development of clinical practice guidelines and guidance statements of the American College of Physicians: Summary of methods. Ann Intern Med 2010;153:194–199.  The GRADE working group. GRADE guidelines—best practices using the GRADE framework. Journal of Clinical Epidemiology [on-line]. Available at http://www.gradeworkinggroup.org/publications/jce\_series.htm |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | 2020 Submission  See the table above for the grade assigned to the recommendation for each medication class.  Strong: Harms, adverse events, and risks clearly outweigh benefits  Weak: Harms, adverse events, and risks may not outweigh benefits |
| Provide all other grades and definitions from the recommendation grading system | N/A |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 2020 Submission  Methods used for the 2019 update were similar to those used in the 2015 update of the Beers Criteria. The American Geriatrics Society formed an expert panel to update the Beers Criteria. The panel worked from the 2015 evidence review and then reviewed any new evidence published since then to update the recommendations in the Beers Criteria. The 2019 review by the AGS 2019 Beers Criteria Update Expert Panel, which this measure is based on, included review of 67 systematic reviews and meta analyses, 29 randomized control trials (RTCs) and 281 observational studies and other types of publications.  Overall, the quality of the evidence for each of the medications included in the Beers Criteria recommendations is good. See table above for the quality of evidence rating for the recommendation for each medication or medication class. The table also includes the AGS 2019 Beers Criteria Update Expert Panel rating for the strength of the evidence supporting each recommendation.  2016 Submission  The Beers Criteria was first published in 1991. Since that time the criteria have been regularly updated based off of the existing criteria and any new evidence published since the last update. The AGS forms an expert panel to update the Beers Criteria every few years. The panel works from the previous evidence review and then reviews any new evidence published since that last review to update the recommendations in the Beers Criteria. The 2015 review by the AGS 2015 Beers Criteria Update Expert Panel, which this measure is based on, included review of 60 systematic reviews and meta analyses, 49 randomized control trials (RTCs) and 233 observational studies and other types of publications.  Overall, the quality of the evidence for each of the medications included in the Beers Criteria recommendations is good. See table under section 1c.16 for the quality of evidence rating for the recommendation for each medication or medication class. The table also includes the AGS 2015 Beers Criteria Update Expert Panel rating for the strength of the evidence supporting each recommendation. Definitions of these ratings are listed in section 1c.21. |
| Estimates of benefit and consistency across studies | 2020 Submission  Each updated study contributes to the strength of the measure by updating the medication lists. The studies consistently mention similar drugs. Since the bodies of evidence all relate to the original Beers list, they maintain consistency in process. Changes to the 2019 Beers Criteria Update improved the clarity of the recommendations and further focused the criteria on medications that are particularly problematic for older adults. Thus, the AGS Beers Criteria continue to be a useful clinical tool to improve medication safety in older adults.  2016 Submission  Each updated study contributes to the strength of the measure by updating the medication lists. See section 1c.16 for a table that contains the Beers Criteria recommendations for each drug and drug class that are included in the measure.Evidence tables containing summaries of each study supporting the recommendations can be found on the American Geriatrics Society’s website: <http://www.americangeriatrics.org/>.  The studies consistently mention similar drugs. Since the bodies of evidence all relate to the original Beers list, they maintain consistency in process. See section 1c.16 for a table that contains the Beers Criteria recommendations for each drug and drug class that are included in the measure. |
| What harms were identified? | 2020 Submission  As part of their review of the evidence, the AGS 2019 Beers Criteria Update Expert Panel identified subgroups of patients who should be exempt from the criteria and for whom listed medications may be appropriate. However, the criteria are unable to account for the complexity of patients and subpopulations; there may be a small portion of individuals who will benefit from use of these medications. The criteria are designed to assist providers in the prescribing of potentially harmful medications and should not be taken as strict criteria to avoid use in all patients without weighing the harms and benefits for individual cases. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | 2020 Submission  To our knowledge there have been no published studies since the systematic review that would impact the recommendations. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**