

AUA White Paper on

# THE BEERS CRITERIA FOR POTENTIALLY INAPPROPRIATE MEDICATION USE IN OLDER ADULTS



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Urological  
Association**

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## **ABSTRACT**

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**Introduction:** Medication-related problems are common but may be preventable outcomes of prescribing choices. Risks associated with medications in the older adult population are greater due to changes in physiologic function with age or disease. Older adults and those with significant comorbidities are often excluded from clinical trials used to develop medications. In 2012, the American Geriatrics Society (AGS) published the most recent update of the Beers Criteria for Potentially Inappropriate Medication (PIM) Use in Older Adults. Several medications included in sections of the Beers Criteria are frequently used in clinical urology, including nitrofurantoin, the alpha<sub>1</sub> blocker medications, and the antimuscarinic anticholinergic medications for the treatment of urge incontinence and overactive bladder. This paper describes the challenges and considerations that are useful in prescribing medications for geriatric patients.

**Methods:** A literature review was performed targeting publications between 2003 and 2013 on the topics of the Beers Criteria, PIMs, and specific urologic medications included in the current version of the Beers Criteria. An expert panel was convened to evaluate this information and create this white paper with the purpose of educating the urologic community on these issues.

**Results:** The rationale for creation and implementation of the Beers Criteria and its implications for urologic practice are reviewed. Careful examination of the Beers Criteria can help clinicians to avoid potentially inappropriate prescribing choices for their geriatric patients. We also identified that the Healthcare Effectiveness Data and Information Set (HEDIS<sup>®</sup>) high-risk medications (HRM) list of PIMs has been implemented as a negative quality indicator, even though this was not an original purpose of the Beers Criteria. In other words, denial of coverage and/or requirements

for preauthorization are being made using the Beers Criteria as justification by third-party payers and other entities.

**Conclusions:** The Beers Criteria were developed to improve prescribing practices for older adult patients in order to reduce or avoid potential risks and complications. We encourage clinicians to educate themselves about the Beers Criteria recommendations and associated initiatives that are aimed at improving the care of our older adult patients. Urologists should play a key role in the development, evaluation, implementation, and analysis of practice measures and the resulting policies.

## **INTRODUCTION: BACKGROUND AND PURPOSE OF THE BEERS CRITERIA**

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Medication-related problems, including adverse drug reactions, drug-to-drug interactions, drug-disease interactions, polypharmacy, and other complications, are common, but may be preventable outcomes of prescribing choices. These problems are particularly common among geriatric patients who tend to be at higher risk for medication-associated complications. In 2012, the American Geriatrics Society (AGS) published the most recent update of the Beers Criteria for Potentially Inappropriate Medication (PIM) Use in Older Adults.<sup>1</sup> The original Beers Criteria published in 1991 were focused specifically on nursing home residents,<sup>2</sup> and subsequent revisions in 1997 and 2003 included expanded considerations of care for older adults in all clinical settings.<sup>3,4</sup> The most recent document is based on an exhaustive, systematic review of the published literature regarding medications and their utility and potential risks versus benefits in older adults, and not simply expert opinion.<sup>1</sup> The writing panel used Institute of Medicine (IOM) methodology for grading the quality of the literature and also assigned a statement regarding the strength of the recommendation for each medication in the listing.<sup>5</sup> The listing categorizes medications into three

primary groups: 1) those to avoid prescribing in older adults; 2) those to avoid in cases of specific drug-disease or drug-syndrome interactions; and 3) those to be used with caution in older adults. It also incorporates and acknowledges specific exceptions for use of PIMs, for example in cases of palliative or end-of-life care. Of note, the AGS plans to conduct systematic reviews and update the evidence and recommendations based on emerging data.

The goal of the Beers Criteria is to improve the effectiveness and safety of prescription practices for geriatric patients. The AGS has noted that the Beers Criteria should never be used to supersede clinical judgment and individualized patient care. The AGS does not endorse the use of the Beers Criteria to certify medications as “never appropriate” for older persons. This is particularly notable, as medications with common properties, such as strong anticholinergic and antimuscarinic effects, are classified by the Beers Criteria as potentially inappropriate medications. Apart from the newer overactive bladder (OAB) medication mirabegron (which was launched after the systematic review was completed for the 2012 Beers Criteria revision), there are currently no other oral pharmaceutical substitutes for the antimuscarinics. The successful management of OAB is challenging, and while behavioral management should be used primarily, the use of these types of medications remains an important part of the management in appropriately selected patients. Indeed, based on both expert opinion and existing published evidence, the Beers Criteria acknowledge that PIMs could be appropriate under certain circumstances with shared decision-making between the prescribing clinician and patient.

Costs and adverse events associated with the use of PIMs are substantial. According to the 2000/2001 Medical Expenditures Panel Survey, the total estimated health cost related to use of

PIMs was \$7.2 billion.<sup>6</sup> Adverse drug events (ADEs) were found to be avoidable in 27 percent of cases in primary care settings and 42 percent of cases in long-term care settings.<sup>7,8</sup>

Adverse drug reactions among older adults can lead to a wide variety of negative outcomes.

Between 2007 and 2009, an estimated 99,628 emergency hospitalizations were required for older adults due to adverse drug reactions.<sup>9</sup> Further, analysis of several national datasets showed that of an estimated 177,504 emergency room visits for adverse drug events in older adults, 3.6 percent were due to medications considered to be “potentially inappropriate for use in older adults” by the 2003 version of the Beers Criteria.<sup>10</sup>

Although older adults, defined herein as those  $\geq 65$  years of age, currently account for approximately 13 percent of the total population in the United States, they receive more than 30 percent of all prescription medications.<sup>11</sup> National data show that overall prescriptions continue to increase, with sharp increases particularly among older adults. In 2007-2008, more than 76 percent of people aged 60 years or older used two or more prescription medications, and 37 percent used five or more.<sup>12</sup> The potential risks associated with medications in this older population may be greater for several fundamental reasons. Changes in physiologic function due to either normal aging or underlying comorbid disease can make beneficial prescribing more challenging in this population. In addition, older adults and those with significant comorbidities are often excluded from clinical trials used to develop and approve medications for commercial use. Therefore, in many situations, it is unclear that the potential benefits of pharmacologic intervention truly outweigh possible risks.

In 2004, Curtis and colleagues conducted a retrospective cohort analysis from a claims database for a large national pharmaceutical benefits manager for outpatient prescriptions.<sup>13</sup> Out of 765,423 patients over 65 years of age, 21 percent filled at least one prescription for a medication of concern under the 1997 Beers Criteria, over 15 percent had prescriptions for two different medications on the list, and 4 percent received prescriptions for three or more concerning medications.

Amitriptyline and doxepin accounted for 23 percent of all claims regarding a drug from the Beers Criteria listing, and oxybutynin accounted for 8.1 percent of the claims. A more recent study examined 597 consecutive acute hospital admissions among older adults with a mean age of  $77 \pm 7$  years.<sup>14</sup> Inappropriate prescribing based on the 2003 Beers Criteria was identified in 32 percent of subjects. Polypharmacy appeared to increase the risk, with those taking more than five medications being at 3.3 times the risk for receiving a drug from the listing. Of those receiving inappropriate prescriptions, 49 percent were admitted to hospital due to an adverse drug event.

Given the complexity and potential risks, the concept of avoiding PIMs and enhancing skillful risk assessment has become central in geriatric prescribing practice. Multiple initiatives have been developed over time to improve the quality of care provided for older adults.

## **THE BEERS CRITERIA AND SPECIFIC MEDICATIONS OF INTEREST TO UROLOGY**

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Several medications commonly used in urologic care are included in the 2012 Beers Criteria Revision. Urologists should be aware of how these medications are classified under the Beers Criteria and what the implications are for clinical practice with older patients. In comparison to prior versions, the 2012 update of the Beers Criteria is more explicit in specifying when and how a given medication or class of drugs may or may not be appropriate for use in older adults. In some cases, the use of select medications should generally always be avoided in older adults. However,

other medications may also be inappropriate, usually due to drug-disease interactions or how the medication is being used. It is important to consider a given patient's underlying comorbid conditions and overall health when selecting these agents.<sup>1</sup> Medications commonly used in urologic practice and the recommendations from the 2012 Beers Criteria are summarized in Tables 1 and 2. Space precludes a comprehensive listing of all medications that could potentially be used in urologic practice, and the reader is referred to the original document outlining the full Beers Criteria for additional details.<sup>1</sup>

### *Nitrofurantoin*

Nitrofurantoin is listed to avoid for long-term antibiotic suppression and in patients with a diminished creatinine clearance (CrCl <60 mL/min).<sup>1</sup> The quality of evidence was graded as moderate, and the strength of recommendation was strong. Chronic administration of nitrofurantoin has been associated with the potential for development of pulmonary toxicity. In addition, diminished renal function can lead to inadequate concentration of the medication in urine.<sup>15</sup> It should be noted that use below a CrCl <60 mL/min is contraindicated in the label of nitrofurantoin.<sup>16</sup> Importantly, the Beers Criteria do not specifically recommend against the use of nitrofurantoin in short courses for treatment of acute cystitis or other urinary tract infection in older adults with adequate renal function. In fact, this medication may be quite useful in this setting, particularly in regional areas where the prevalence of quinolone-resistant *Escherichia coli* is high. Nowhere in the Beers Criteria does it state that nitrofurantoin should never be used or not reimbursed.



### *Meperidine*

Meperidine is included in the Beers Criteria to always avoid in older adults for several reasons.<sup>1</sup> It is poorly effective as an analgesic agent in dosages commonly used; it can lead to accumulation of a metabolite that can be neurotoxic and increases the risk of delirium and other complications; and safer and more effective alternatives are readily available. The quality of evidence was rated as moderate and the strength of recommendation was strong.

### *Alpha Blocker Medications*

The alpha blocker medications doxazosin, prazosin, and terazosin are listed as medications to avoid specifically for use as *antihypertensive* medications and in women with stress or mixed urinary incontinence, but these medications are acceptable for the treatment of lower urinary tract symptoms (LUTS).<sup>1</sup> The recommendations were based on the high risk of orthostatic hypotension and the strong epidemiological association between alpha blockers and incontinence in women, as well as the availability of alternative agents and treatments with superior risk/benefit profiles. The quality of evidence was rated as moderate, and the strength of recommendation was strong.

### *Antimuscarinic Agents for Overactive Bladder and Urgency Incontinence*

The oral antimuscarinic agents used in the treatment of OAB and urgency urinary incontinence are included in the 2012 Beers Criteria to avoid in two specific patient populations: older persons with constipation, and older persons with delirium, dementia or cognitive impairment.<sup>1</sup> These medications include darifenacin, fesoterodine, oral oxybutynin, solifenacin, tolterodine, and trospium. It is noted that these medications can worsen constipation, that responses can be variable, and that alternative agents should be considered if the medication is used and constipation develops. The quality of evidence was rated as high, and the strength of the

recommendation was classified as weak. The quality of evidence supporting the association of these medications with delirium was moderate, and the recommendation was strong. It is important to note that prior recommendations in the 2003 Beers Criteria to avoid antimuscarinics in men with a history of benign prostatic hyperplasia (BPH) or bladder outlet obstruction were removed from the most recent 2012 version.<sup>14</sup> This is because of interval data documenting the safety and efficacy of antimuscarinics in men with symptomatic BPH.

### *Other Anticholinergic Medications*

It was recommended that strongly anticholinergic medications, including inhaled anticholinergic drugs used primarily for the treatment of chronic obstructive pulmonary disease (COPD), be avoided in men with a history of LUTS and BPH due to the risk of urinary retention.<sup>1</sup> This specifically does not include the oral antimuscarinic medications listed in the prior paragraph. The quality of evidence was moderate, and the recommendation considered weak, except for inhaled anticholinergics where the recommendation was considered strong.

Medications with strong anticholinergic properties received special consideration in the most recent Beers Criteria because of their association with significant and morbid adverse effects in older adults, and the general overuse and misuse of this class of drugs. Examples range from dry mouth, constipation, dry eyes, and visual disturbance to cognitive impairment. The 2012 Beers Criteria Revisions includes a list of medications with strong anticholinergic properties that should be used with caution in older adults.<sup>1</sup> In addition to the antimuscarinics discussed previously, this list includes antihistamines (diphenhydramine, hydroxyzine, meclizine); antidepressants (amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline, paroxetine); antispasmodics (belladonna alkaloids, dicyclomine, hyoscyamine products, propantheline,

scopolamine); anti-Parkinson agents, antipsychotics, and skeletal muscle relaxants. It should be emphasized that inclusion in this listing does not mean that the medication should *never* be used in older adults, but that the medication is potentially inappropriate and should be avoided considering the potentially strong anticholinergic properties and associated adverse effects.

### *Hormonal Medications (Estrogens and Testosterone)*

According to the 2012 Beers Criteria, systemic administration of oral or transdermal estrogens should be avoided in women with a history of urinary incontinence, due to the evidence that estrogen can aggravate incontinence symptoms in these patients.<sup>1</sup> The quality of evidence was high, and the recommendation considered strong. In contrast, the Beers Criteria supports the use of topical vaginal estrogens for the treatment of vaginal dryness, atrophic vaginitis, dyspareunia, risk reduction of urinary tract infections, and LUTS associated with vaginal symptoms.

Testosterone and methyltestosterone are included as medications to avoid in older men due to the associated potential for cardiac problems, and they are contraindicated in men with prostate cancer.<sup>1</sup> It was noted that these should be avoided unless clinically indicated for the treatment of moderate-to-severe symptomatic hypogonadism. The quality of evidence was rated as moderate, and the strength of recommendation was considered weak.

## **HEALTH POLICY IMPLICATIONS**

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The AGS is fully cognizant of how the prior versions of the Beers Criteria have been applied in the past to health policy decisions.<sup>17</sup> Starting in 1999, the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services [CMS]) incorporated the existing Beers Criteria as a quality indicator in the federal regulations in nursing homes, which is used in annual mandated

state surveys. This incorporation into a federal regulatory quality measure effectively removed the concept of “potentially inappropriate” from PIMs, thus making the listed drugs simply “inappropriate” and by inference never to be used. The introduction of Medicare Part D for prescription coverage in 2006 subsequently increased the federal and payer focus on quality prescribing for older adults.

In 2003, the National Committee for Quality Assurance (NCQA) adapted the 2003 Beers Criteria for the definition of high-risk medications (HRMs) into its Healthcare Effectiveness Data and Information Set (HEDIS)<sup>®</sup>,<sup>18</sup> which is used by more than 90 percent of American health care plans to measure performance on important quality dimensions of care and service. This created a frequently misunderstood link between the Beers Criteria and use of quality data for Relative Resource Use, in essence the data used or reimbursement based on quality and value. While the Beers Criteria specifies *potentially inappropriate* medications, the HEDIS<sup>®</sup> HRM medication list is implemented as a negative quality indicator. It implies that these medications *should not be used*.

NCQA was granted deeming authority for the Medicare Advantage (MA) Program, which allows them to review MA organizations in six key categories, one of them being quality assurance. In addition, the use of the Beers Criteria in the HEDIS<sup>®</sup> measures affects the Medicare Part C Medicare Advantage Program in that these measures are used to assess Medicare Star Ratings for insurance companies. The Star Ratings support pay-for-performance bonuses that help high-value plans compete for better benefits and costs. According to a comment letter to the director of CMS Medicare Drug Benefit and C&D Data Group from NCQA, the NCQA State of Healthcare Quality 2012 report findings indicate that Star Rating pay-for-performance may be getting results with decreases in the use of high-risk medications. According to the president of the NCQA,

“Given the substantial competitive advantages that Star Ratings now provide to highly rated plans, these early results may portend even greater future improvement.”<sup>19</sup>

It must be understood that the link between HEDIS® HRMs and reimbursement pertains solely to patient care services in quality-based insurance models and CMS contracting agreements. The decisions to include or exclude medications from specific formularies are separate cost-based decisions by insurers and their pharmacy benefit managers.

All of these initiatives and measures follow similar general principles of identifying medications that may be potentially inappropriate for use in older adults. However, while AGS used the 2011 IOM standard for guideline development, the 2012 Beers Criteria Revision appears to be unique in its combination of evidence-based analysis for panel decisions, specified and widely accepted levels of evidence, and having an open public comment period before finalization of the measure set.<sup>20</sup>

Researchers have analyzed the potential relationship between quality of prescribing based on the previous versions of the Beers Criteria and other methods and clinical outcomes. Stockl and colleagues conducted a retrospective case-control analysis of 37,358 matched pairs of older adults who were or were not receiving PIMs as defined by the 2003 Beers Criteria.<sup>21</sup> Patients receiving a strongly anticholinergic medication were more likely to experience a fall or fracture compared to controls (hazard ratio, 1.22; 95 percent confidence interval, 1.10-1.35). Other adverse events also occurred significantly more often in those receiving PIMs. Adjusted annual medical and total health care costs were higher for any patient using PIMs evaluated in this study compared to control subjects.

Lund and colleagues found that adherence to the Beers Criteria in prescribing served as a proxy not only for measurement of the specific medications on the listing, but as a more global measure of prescribing quality among clinicians caring for older adults.<sup>22</sup> They noted that use of these types of measures could help to identify patients who might be candidates for more comprehensive medication review and reconciliation. They concluded that future interventional programs could target application of the Beers Criteria and other integrated quality indicators.

In systematic review published in 2007, Jano and colleagues examined the clinical outcomes of Beers Criteria application in a variety of healthcare settings.<sup>23</sup> They found that increased adverse drug reactions and healthcare costs were associated with prescription of PIMs as defined by the 1991, 1997, and 2003 versions of the Beers Criteria.

### **REACTION AND RESPONSE TO THE 2013 BEERS CRITERIA REVISION**

A cross-sectional analysis of prescribing of HRMs from the 2006 HEDIS<sup>®</sup> Quality Measure for older adults was implemented in Veterans Affairs medical centers.<sup>18</sup> These researchers found that 19.6 percent of older veterans received at least one HRM, with the three most common categories being antihistamines, opioid analgesics, and skeletal muscle relaxants. Patients receiving 10 or more medications (polypharmacy) were at the greatest risk of exposure to HRMs. The authors concluded that the results were similar to those from a previous analysis of the use of 1997 Beers Criteria medications in this population, and that despite the considerable risk of adverse events in older adults, prescribing patterns had not changed substantially over time. A number of peer-reviewed editorials have appeared in the literature noting both potential benefits and concerns regarding the 2012 Beers Criteria Revision recommendations. The co-chairs of the 2012 Revision panel noted that, “The Beers Criteria remain simultaneously one of the most used and most

controversial sets of medication criteria in the world. Although not without limitations, the Beers Criteria have done more than any other tool in the past decade to improve the awareness of and clinical outcomes for older adults with polypharmacy and for the most vulnerable older adults at risk of adverse drug events.<sup>24</sup> They highlighted the potential to include these types of recommendations in electronic medical record systems to reduce risks and harms. They also noted the need for a listing of alternative medications that clinicians could use in cases in which there is a recommendation to avoid certain drugs, and the AGS is currently working on such a listing. They emphasized the basic concept in geriatric prescribing of “less is often more,” particularly with regard to avoiding polypharmacy, PIMs, and their associated negative outcomes.

Resnick and Pacala noted that CMS has adopted earlier versions of the Beers Criteria in quality assessment of pharmacological care in older adults and has incorporated the criteria into Medicare Part D, which applies to prescription drug coverage for older adults.<sup>17</sup> Beier emphasized, “...the practicing clinician needs to be vigilant and keep up to date with emerging evidence of efficacy and safety that may inform future dosing and duration of therapy decisions.”<sup>25</sup> Indeed, as understanding of medication efficacy, safety, indications, and contraindications evolves over time, practice patterns for medications change. What was common practice when one was in clinical training can change drastically with time, and new knowledge must be incorporated into daily practice based on emerging evidence. This has been addressed very well in the most recent revision of the Beers Criteria. The new version also retains the patient-centered approach, and the criteria apply across various places and types of clinical care. In an editorial examining the Beers Criteria specifically as they apply to urology, Griebeling noted the need for practitioners to be aware of the specific details of the Beers Criteria and how they might apply to practice.<sup>26</sup> He also noted the growing

demographics of geriatrics in urology and the fact that the volume of care for older adults in urology is one of the highest among all specialties.

### **ADDITIONAL HEALTHCARE IMPLICATIONS OF THE BEERS CRITERIA**

The stated intentions of the 2012 Beers Criteria include “improving the selection of prescription drugs by clinicians and patients, evaluating patterns of drug use within populations, educating clinicians and patients on proper drug usage, and evaluating health outcome, quality of care, cost and utilization data.”<sup>1</sup> Practicing clinicians remain the primary educational target audience for the Beers Criteria. The criteria are intended to serve as a road map for those who are looking to ensure that older adults receive the best care possible within the context of a relative paucity of evidence on these drugs specifically in the geriatric population. Use of the Beers Criteria for value-based reimbursement (incorporating incentives based on quality of care) and regulation go beyond these intentions, as well as the explicit position of the AGS. Further, according to the authors of the Beers Criteria, “these criteria are not meant to be applied in a punitive manner.”<sup>1</sup>

One of the other issues often, yet erroneously, linked to the Beers Criteria is actions by third-party or other payers to deny coverage for certain prescriptions or to require clinicians to obtain preauthorization. This can have a substantial impact on practitioner and staff time for individual practitioners. An example would be a request for preauthorization for nitrofurantoin prescribed as a five-day course to treat acute cystitis in an older adult with normal renal function. The use of nitrofurantoin in this circumstance is clearly consistent with the recommendations of the 2012 Beers Criteria (avoid nitrofurantoin only for use as cystitis suppression lasting over six months or in patients with impaired renal function). The basis of the need for preauthorization likely stems from



its inclusion on the HEDIS® HRM list, yet the Beers Criteria are often assumed to be the justification for this additional prescription and approval burden.

Of similar concern is the use of the Beers Criteria as a marker of quality of care. While this process may be acceptable if the Beers Criteria are correctly interpreted and applied to a given clinical scenario, it raises substantial concerns if the Beers Criteria are adopted as a “do not use” list or are generalized to other clinical situations. Potential linkage of the HRMs, without redress, to value-based reimbursement systems such as pay-for-performance models is of particular concern. As noted in the prior example, use of a short course of nitrofurantoin to treat a case of acute cystitis in an older adult with normal renal function would be appropriate prescribing under the Beers Criteria, yet could potentially be classified as poor quality care by quality measures based on HEDIS® HRMs or other related measures; this could have significant negative ramifications.

In addition, written notifications to providers are often generated automatically by pharmacies for patients who are on one or more of the medications listed in the Beers Criteria, even if the prescription is appropriate under the specific context of the Beers Criteria. These notices are typically sent by pharmacies or pharmaceutical benefits managers and provide a listing of all medications the older adult is using. This often can be very useful information that could alert a provider to potential medication duplications or interactions, or could suggest alternate options. However, in many cases medications in the Beers Criteria that are considered HRMs may inappropriately trigger a denial without taking other factors into account, such as lack of drug-disease interactions or other patient-specific issues. For example, it is common to receive notifications when a patient is taking an antimuscarinic medication for treatment of overactive bladder symptoms even in the absence of a history of constipation. While use of these medications

in this instance is clearly acceptable within the 2012 Beers Criteria, the notification generally ignores the qualification that this drug is inappropriate specifically in the setting of concurrent constipation. Similarly, the alpha blocker medications, including doxazosin, prazosin, and terazosin, are listed in the Beers Criteria to avoid for use as antihypertensive medications; they are not listed regarding their use to treat LUTS and are considered appropriate within this context.

In some cases, the provider is expected to respond to the notice in writing. While timely reminders of potentially inappropriate drug prescriptions are the goal of this practice, this increases the burden of time and work required on the part of the clinician and his/her staff to justify an appropriate prescription. Medications on the Beers Criteria may be denied because they also are listed on the HRM list, or because the electronic health record cannot take into consideration the reason why the medication is being prescribed, nor the thoughtful shared medical decision process between the physician and patient for the appropriate treatment of their condition.

## **COVERAGE AND FORMULARY STATUS ISSUES**

Guidance that is intended to steer and support individual clinicians in making treatment decisions should not be the basis for making formulary decisions that could have a negative impact on individual patients for whom the benefit of the drug would outweigh the risks identified in the criteria. Yet decisions regarding formulary status for specific medications are typically made between insurance and care providers and pharmaceutical manufacturers and include a variety of factors, including drug cost, clinical utility, and multiple drug contracts between these entities. The Beers Criteria do not address or consider such factors, yet there remains a concern that formulary decisions are potentially being made under the guise of falling within the recommendations of the Beers Criteria. Indeed, one of the most time-consuming issues facing practicing clinicians is the

need to alter or change medication prescriptions or to obtain insurance preapproval for certain medications based on a patient's insurance coverage. A common example includes the antimuscarinic medications used in the treatment of overactive bladder. Neither the Beers Criteria nor the most recent AUA guideline on this topic specify any type of preferential hierarchy for these medications, as no appreciable hierarchy has been discernible in high-quality scientific literature.<sup>1,27</sup> However, if a clinician prescribes a brand name medication for a given condition, and this is denied by the insurance provider in favor of a generic option, this is generally due to contracting and formulary decisions made by the payer for this class of medications; such considerations are NOT specifically within the domain of the Beers Criteria.

## **FUTURE IMPLICATIONS AND RECOMMENDATIONS**

Due to the paucity of data, the need for additional research on drug effectiveness and safety in older adults – particularly for medications used in urologic care – is clear. This lack of evidence is based on the underlying bias to exclude older adults from clinical trials used to approve medications and a lack of follow-up studies on the use and side effects of these medications specifically in older adults.<sup>28</sup> We encourage future research that specifically targets and includes older adult subjects in medication development and outcomes analysis. We also recommend future research on existing medications for which definitive data on utility and safety in older adults may be lacking. This may help clarify potential benefits and risks of select medications, such as nitrofurantoin, which are commonly used in urologic practice. This will help to improve our understanding of the efficacy of medications in this complex and often vulnerable population. In turn, development of evidence will help to improve prescribing and clinical outcomes in this population and provide enhancements to the future refinement of the Beers Criteria.

Research on drug outcomes related to effectiveness, adverse events, and ease of use will improve the quality of medication prescribing for older adults. This includes use of a reliable method to directly link administration of a given medication with adverse clinical events. In addition, methods are needed to examine the use of a prescribing appropriateness tool and subsequent clinical outcomes.<sup>29</sup> This includes not only direct individual prescription outcomes, but rigorous methods to analyze outcomes at larger system and policy levels.

Development of a point-of-care listing for alternative medication options – when different drugs are available – that could be used instead of medications on the Beers Criteria list could be extremely helpful for clinicians.<sup>24</sup> Electronic medical record algorithms are being tailored to help with this process and have shown positive results.<sup>30</sup> Nurse-led initiatives have also been shown to be effective in reducing potentially inappropriate prescribing in the community hospital setting.<sup>31</sup> Numerous reference materials, databases, and electronic resources regarding individual medications are available to help clinicians with complex prescribing decisions.

Urologists will play a key role in the development, evaluation, implementation, and analysis of these types of measures and the resulting policies. With regard to practice and policy, the AUA will continue to work with other professional organizations such as the AGS, CMS, commercial third-party insurers, and the pharmaceutical industry to evaluate and adapt to changing knowledge within the field of geriatric urology.

We strongly encourage clinicians, payers, pharmacy benefit managers, and policy makers to educate themselves about the reasoning and recommendations contained within the Beers Criteria as they apply to urologic medications and practice with older adults. A thorough understanding of

how and why recommendations were made for each medication in question can help to guide prescribing selections in this patient population. Specifically, appreciating which medications should generally be avoided in essentially all geriatric patients versus those to avoid in specific circumstances will reduce inappropriate prescriptions and the resulting potential adverse events. We encourage urologic clinicians, researchers, and policy experts to actively participate in the public review and comment that will be associated with the ongoing updates of the Beers Criteria. The ultimate goal of the Beers Criteria and associated initiatives is to improve the care of our older adult patients.

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Table 1. Medications commonly used in urologic practice included in the 2012 Beers Criteria (adapted from <sup>1</sup>)

Medication	Recommendation	Rationale	Quality of Evidence	Strength of Recommendation
Anti-infective <ul style="list-style-type: none"> <li>Nitrofurantoin</li> </ul>	Avoid for long-term suppression; avoid in patients with CrCl <60 mL/min	Potential for pulmonary toxicity; safer alternatives available; lack of efficacy in patients with CrCl <60 mL/min due to inadequate drug concentration in the urine	Moderate	Strong
Alpha Blockers <ul style="list-style-type: none"> <li>Doxazosin</li> <li>Prazosin</li> <li>Terazosin</li> </ul>	Avoid use as an antihypertensive	High risk of orthostatic hypotension; not recommended as routine treatment for hypertension; alternative agents have superior risk/benefit profile	Moderate	Strong
Tertiary TCAs*, alone or in combination <ul style="list-style-type: none"> <li>Amitriptyline</li> <li>Imipramine</li> </ul>	Avoid	Highly anticholinergic, sedating, and cause of orthostatic hypotension	High	Strong
First-generation antihistamines* (as single agent or as part of combination products) <ul style="list-style-type: none"> <li>Diphenhydramine (oral)</li> <li>Hydroxyzine</li> <li>Promethazine</li> </ul>	Avoid	Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as a hypnotic; greater risk of confusion, dry mouth, constipation, and other anticholinergic effects and toxicity; Use of	Hydroxyzine and promethazine: high; All others: moderate	Strong

		diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate		
Androgens <ul style="list-style-type: none"> <li>• Methyltestosterone</li> <li>• Testosterone</li> </ul>	Avoid unless indicated for moderate to severe hypogonadism	Potential for cardiac problems; contraindicated in men with prostate cancer	Moderate	Weak
Estrogens with or without progestins	Avoid oral or topical patch; topical vaginal cream is acceptable to use low-dose intravaginal estrogen for the management of dyspareunia, lower urinary tract infections and other vaginal symptoms	Evidence of carcinogenic potential (breast and endometrium); lack of cardioprotective effect and cognition protection in older women; evidence that vaginal estrogens for treatment of vaginal dryness is safe and effective in women with breast cancer, especially at dosages of estradiol <25 mcg twice weekly	Oral and patch: high Topical: moderate	Oral and patch: strong Topical: weak
Pain medications <ul style="list-style-type: none"> <li>• Meperidine</li> </ul>	Avoid	Not an effective oral analgesic in dosages commonly used; may cause neurotoxicity; safer alternatives available	High	Strong

CrCl = creatinine clearance

TCAs = tricyclic antidepressants

\*Only medications prescribed by urologists are listed as examples. A comprehensive list of medications can be found at [http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria\\_JAGS.pdf](http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria_JAGS.pdf).<sup>1</sup>

Table 2. Medications commonly used in urologic practice included in the 2012 Beers Criteria to avoid due to specific drug-disease or drug-syndrome (adapted from <sup>1</sup>).

Disease or Syndrome	Drug	Recommendation	Rationale	Quality of Evidence	Strength of Recommendation
Delirium	<ul style="list-style-type: none"> <li>• All TCAs</li> <li>• Anticholinergics</li> <li>• Benzodiazepines</li> <li>• Chlorpromazine</li> <li>• Corticosteroids</li> <li>• H<sub>2</sub>-receptor antagonists</li> <li>• Meperidine</li> <li>• Sedative hypnotics</li> <li>• Thioridazine</li> </ul>	Avoid	Avoid in older adults with or at high risk of delirium because of inducing or worsening delirium in older adults; if discontinuing drugs used chronically, taper to avoid withdrawal symptoms	Moderate	Strong
Dementia and cognitive impairment	<ul style="list-style-type: none"> <li>• Anticholinergics</li> <li>• Benzodiazepines</li> <li>• H<sub>2</sub>-receptor antagonists</li> <li>• Zolpidem</li> <li>• Antipsychotics, chronic and as-needed use</li> </ul>	Avoid	Avoid because adverse CNS effects; avoid antipsychotics for behavioral problems of dementia unless nonpharmacological options have failed and the patient is a threat to themselves or others; antipsychotics are associated with an increased risk of cerebrovascular accident (stroke) and mortality in persons with dementia	High	Strong
Chronic constipation	<p>Oral antimuscarinics for urinary incontinence *</p> <ul style="list-style-type: none"> <li>• Darifenacin</li> <li>• Fesoterodine</li> <li>• Oxybutynin (oral)</li> </ul>	Avoid unless no other alternatives	Can worsen constipation; agents for urinary incontinence; antimuscarinics differ in incidence of constipation; response	For urinary incontinence: high All others: moderate to low	Weak

	<ul style="list-style-type: none"> <li>• Solifenacin</li> <li>• Tolterodine</li> <li>• Trospium</li> </ul>		variable; consider alternative agent if constipation develops		
Urinary incontinence (all types in women)	Estrogen oral and transdermal (excludes intravaginal estrogen)	Avoid in women	Aggravation of incontinence	High	Strong
Lower urinary tract symptoms benign prostatic hyperplasia	Inhaled anticholinergic agents; strongly anticholinergic drugs, except antimuscarinics for urinary incontinence	Avoid in men	May decrease urinary flow and cause urinary retention	Moderate	Inhaled agents: strong All others: weak
Stress or mixed urinary incontinence	Alpha Blockers <ul style="list-style-type: none"> <li>• Doxazosin</li> <li>• Prazosin</li> <li>• Terazosin</li> </ul>	Avoid in women	Aggravation of incontinence	Moderate	Strong

TCA = tricyclic antidepressants

\* Only medications prescribed by urologists are listed as examples. A comprehensive list of medications can be found at [http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria\\_JAGS.pdf](http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria_JAGS.pdf).<sup>1</sup>

Table 3. Acceptable urologic indications for specific medications identified in The Beers Criteria for Potentially Inappropriate Medication for Use in Older Adults (developed by the AUA Beers Criteria White Paper Workgroup based on <sup>1</sup>).

Medication	Urologic Indication
Nitrofurantoin	<ul style="list-style-type: none"> <li>• Acute treatment of uncomplicated urinary tract infection without systemic symptoms in individuals living in communities with an identified high risk of quinolone-resistant organisms OR due to multiply-resistant bacteria with identified sensitivity to nitrofurantoin</li> </ul>
Alpha-blockers	<ul style="list-style-type: none"> <li>• Medical management of bothersome benign prostate enlargement symptoms while monitoring for efficacy and adverse events</li> </ul>
Estrogens	<ul style="list-style-type: none"> <li>• Topical (vaginal) use for symptomatic vaginal atrophy due to low estrogenic states</li> <li>• Risk reduction for chronic recurrent urinary tract infections in post-menopausal women</li> </ul>
Anti-muscarinics	<ul style="list-style-type: none"> <li>• Trial of antimuscarinics is appropriate as second line therapy in patients with high bother from overactive bladder symptoms, with monitoring of benefits, risks, and adverse effects for that individual patient<sup>27</sup></li> <li>• Trial of antimuscarinics is appropriate for male patients with benign prostatic enlargement in whom the symptom complex includes high bother from urgency and frequency symptoms in the absence of significant urinary retention (post-void residual urine volume &lt;200 mL) and in patients for whom first-line therapy for OAB fails<sup>27</sup></li> </ul>