

## October 23, 2013 DURB Meeting Summary

Issue	Page; Tab	Action	Notes
Roll Call			Present: Dr. Swee, Dr. Zanna, Dr. Gochfeld, Ms. Olson, Dr. Barberio, Dr. Marcus, Dr. Goen, Mr. Schafer, Dr. Lind (ex officio). Unable to attend: Dr. Moynihan, Dr. Moore
Review of Minutes	Pages 3-10; Tab 1	Approved	Minutes from June 26, 2013 meeting was reviewed and approved. The approved meeting summary will also be posted on the DURB website at: <a href="http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html">http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html</a>
Secretary's Report	Page 11; Tab 2		<ul style="list-style-type: none"> <li>• Educational newsletter on Type 2 diabetes treatment options is awaiting the Medicaid Director's signature. Dr. Swee requested that a copy should be mailed to each Board member prior to distribution.</li> <li>• The draft of the DURB Annual Report for State Fiscal Year 2013 was emailed to Board members prior to the meeting. The State is requesting comments or feedback by November 30, 2013.</li> <li>• Some of the HMOs provided responses to the Board's questions during protocols review.</li> <li>• HealthFirst, one of the NJ HMOs was acquired by WellCare. Transaction will be completed in January 1<sup>st</sup> 2014.</li> <li>• No update on replacement for three positions in the DURB membership.</li> </ul>
<b>Old Business</b>			
1. HMO Response to Protocols Review Questions	Page 13-15; Tab 3		<ul style="list-style-type: none"> <li>- The Board reviewed responses to some of their questions in the June meeting. Board members still expressed concern about some of the indications that were not covered by the HMOs due to lack of FDA's explicit "support" for these indications but are covered in the fee for service protocols. To alleviate the burden on the provider of providing literature support, Dr. Swee suggested that the State should develop a library of literature to help support the prescribers' decisions. Dr. Lind, Medicaid's Medical Director will be in charge of developing the library. The Board requested a report/update on the process at the next meeting.</li> <li>- The Board also expressed concern about restricting the use of some medications by speciality of the prescriber.</li> </ul>

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<p><b>New Business</b></p> <p>A. Long-Acting Beta-agonists Newsletter</p>	<p>Page 17-19; Tab 4</p>	<p>Approved</p>	<p>The Board reviewed and approved an educational newsletter on long-acting beta-agonists, medications used for the treatment of asthma and chronic obstructive pulmonary disease or COPD. As requested by members, formatting to two pages instead of current three will be done prior to distribution.</p>
<p>B. Protocols Review</p>	<p>Biologic Response Modifiers: Pages 21-27; Tab 5</p>		<p>The Board reviewed the protocols for biologic response modifiers (BRMs). Dr. Swee referenced an email from Dr. Moynihan, a rheumatologist, who requested that all the plans should include ankylosing spondylitis as one of their covered indications. Most did. She also requested that BRMs should be considered for uveitis not responding to conventional treatment. Members thought that this should be an exception and not part of the list of indications. Other concerns expressed by board members:</p> <ul style="list-style-type: none"> <li>- Specialty prescribers required by HMO plans: The State will work with the HMOs to provide more access for patients.</li> <li>- Step therapy: The Board had no objection to step therapy but requested that there should be a report to monitor how often patients had to use stepped therapy to obtain needed treatment.</li> </ul>
	<p>Dronedarone (Multaq®): Pages 28-30; Tab 5</p>		<p>Fee for service (FFS) does not have a protocol for this product. A report for General Assistance (GA) population confirmed low utilization - 127 claims in the first half of 2011 and 35 claims in the first half of 2012.</p>
	<p>Human Growth Hormones: Pages 31-45; Tab 5</p>		<p>No specific changes or requests were made.</p>
	<p>Palivizumab (Synagis®): Pages 46-49; Tab 5</p>		<p>Chris Dube, a medical representative with Medimmune pointed out that Plan (A) did not incorporate a 2012 guideline that recommended treatment for children with congenital or neuromuscular disease regardless of prematurity. The State will follow up with the HMO.</p>
	<p>Protease Inhibitors for Hepatitis C: Pages 50-53; Tab 5</p>		<p>Dr. Swee again expressed his concern about HMO plans restriction of use of these products to specialists.</p>

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<b>Informational Highlights/Reports</b> 1. Molina Medicaid Solutions (Fee-for-Service) Prior Authorization Report	Pages 55-61; Tab 6		<p>The Board reviewed a new prior authorization report comparing all HMO plans including FFS for the 2<sup>nd</sup> quarter of 2013. There were discrepancies on the number of prior authorized claims and percentages of denials. Sam Currie, director of pharmacy at Horizon NJ Health explained that these differences will persist due to divergent parameters, denominators, and operational differences among the plans.</p> <p>For Molina's Medical Exceptions Program (MEP) during this period there were 2,805,747 pharmacy claims processed; 73,616 (2.6%) prior authorization requests and 9,762 (13.3%) denials. The top four categories of denials were: (1) Clinical Criteria Not Met, (2) Incorrect Day Supply, (3) Therapeutic Duplication, and (4) MNF Not Returned by Prescriber (MNFNR).</p>
2. HMO 2 <sup>nd</sup> Quarter Reports			<p>For the HMOs, denial percentages ranged from 0.6% to 40%. This discrepancy in range was addressed above.</p>
3. Summary of DURB Action Items	Page 63; Tab 7	Update	<p>In this meeting, Dr. Marcus questioned the low utilization of the product approved for HIV prophylaxis. Mr. Vaccaro explained that there is no identifier for patients that fall into this category on the FFS population. The HMOs also have diagnosis-capturing issues too. Dr. Zanna will request Dr. Paul's presence in the next meeting to address this question.</p> <p>The T2DM educational newsletter is now awaiting Medicaid Director's signature.</p>
October 2012: Protocol for HIV PrEP			
June 2013: Educational newsletter			

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4. DHS and DHSS Programs' Top Drugs Report	Pages 65-77; Tab 8		<p>August 2013 report of the top drugs, by dollar amount, claims count and service units were presented. HIV medications represented the top ten drugs in the list for "ALL population" (92%). Abilify, an atypical antipsychotic made up 8% in this category.</p> <p>Dr. Marcus requested an additional column in the report that will show changes in the ranking of the drugs from month to month (or meeting to meeting). Dr. Swee made a request to Dr. Marcus to provide a report that showed the top drugs (ingested) from the Poison Control Center database.</p>
5. Medication Information	Pages 79-84; Tab 9		<p>The following information were included in the Board's meeting package:</p> <p>(a) NJ Prescription Monitoring Program</p> <p>The Board discussed the benefits and limitations of the NJ Prescription Monitoring Program. The program, a new tool established in 2010 helps in the effort to halt the abuse and diversion of prescription drugs. The limitations however include physicians and pharmacists that cannot access the system because they are not involved in "direct patient care"; healthcare payors that are not authorized to use the system; and eligible pharmacy providers that opt out of the system. Dr. Paul will also address this issue at the next meeting.</p> <p>(b) New APA guidelines on cutting antipsychotic overuse</p> <p>Dr. Gochfeld distributed a more detailed handout from the American Psychiatric Association which discussed "five things physicians should question" prior to prescribing antipsychotic medications.</p> <p>(c) FDA approves new DPP-4 Inhibitor Alogliptin (Nesina®) for T2DM</p> <p>(d) FDA approves dolutegravir (Tivicay®) for HIV infection</p>

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<p>Follow up items:</p> <p>(a) Develop a literature of library</p>			<ul style="list-style-type: none"> <li>- Dr. Lind will lead the process of developing a library of literature to help providers with information that support off-label prescribing when necessary.</li> </ul>
<p>(b) Update Synagis® protocol</p>			<ul style="list-style-type: none"> <li>- HMO plan "A" to update Synagis® protocol with 2012 information</li> </ul>
<p>(c) Provide denials information in Excel format</p>			<ul style="list-style-type: none"> <li>- Dr. Marcus requested that the denials report should be presented in Excel format for comparison</li> </ul>
<p>(d) Add NJ Prescription Monitoring Program to next meeting agenda</p>			<ul style="list-style-type: none"> <li>- Continue discussion about the NJ Prescription Monitoring Program (PMP) at the next Board meeting</li> </ul>
<p>(e) Compare ranking of the top 25 drugs</p>			<ul style="list-style-type: none"> <li>- Provide previous meeting's ranking of the Top 25 drugs to be compared with current meeting's ranking</li> </ul>
<p>(f) Add pre-exposure prophylaxis to next meeting agenda</p>			<ul style="list-style-type: none"> <li>- Continue discussion about use of drug(s) for pre-exposure prophylaxis (PrEP) at the next Board meeting (Dr. Paul)</li> </ul>

## Five Things Physicians and Patients Should Question

1

### Don't recommend percutaneous feeding tubes in patients with advanced dementia; instead offer oral assisted feeding.

Careful hand-feeding for patients with severe dementia is at least as good as tube-feeding for the outcomes of death, aspiration pneumonia, functional status and patient comfort. Food is the preferred nutrient. Tube-feeding is associated with agitation, increased use of physical and chemical restraints and worsening pressure ulcers.

2

### Don't use antipsychotics as first choice to treat behavioral and psychological symptoms of dementia.

People with dementia often exhibit aggression, resistance to care and other challenging or disruptive behaviors. In such instances, antipsychotic medicines are often prescribed, but they provide limited benefit and can cause serious harm, including stroke and premature death. Use of these drugs should be limited to cases where non-pharmacologic measures have failed and patients pose an imminent threat to themselves or others. Identifying and addressing causes of behavior change can make drug treatment unnecessary.

3

### Avoid using medications to achieve hemoglobin A1c <7.5% in most adults age 65 and older; moderate control is generally better.

There is no evidence that using medications to achieve tight glycemic control in older adults with type 2 diabetes is beneficial. Among non-older adults, except for long-term reductions in myocardial infarction and mortality with metformin, using medications to achieve glycated hemoglobin levels less than 7% is associated with harms, including higher mortality rates. Tight control has been consistently shown to produce higher rates of hypoglycemia in older adults. Given the long timeframe to achieve theorized microvascular benefits of tight control, glycemic targets should reflect patient goals, health status, and life expectancy. Reasonable glycemic targets would be 7.0 – 7.5% in healthy older adults with long life expectancy, 7.5 – 8.0% in those with moderate comorbidity and a life expectancy < 10 years, and 8.0 – 9.0% in those with multiple morbidities and shorter life expectancy.

4

### Don't use benzodiazepines or other sedative-hypnotics in older adults as first choice for insomnia, agitation or delirium.

Large scale studies consistently show that the risk of motor vehicle accidents, falls and hip fractures leading to hospitalization and death can more than double in older adults taking benzodiazepines and other sedative-hypnotics. Older patients, their caregivers and their providers should recognize these potential harms when considering treatment strategies for insomnia, agitation or delirium. Use of benzodiazepines should be reserved for alcohol withdrawal symptoms/delirium tremens or severe generalized anxiety disorder unresponsive to other therapies.

5

### Don't use antimicrobials to treat bacteriuria in older adults unless specific urinary tract symptoms are present.

Cohort studies have found no adverse outcomes for older men or women associated with asymptomatic bacteriuria. Antimicrobial treatment studies for asymptomatic bacteriuria in older adults demonstrate no benefits and show increased adverse antimicrobial effects. Consensus criteria has been developed to characterize the specific clinical symptoms that, when associated with bacteriuria, define urinary tract infection. Screening for and treatment of asymptomatic bacteriuria is recommended before urologic procedures for which mucosal bleeding is anticipated.

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## Five More Things Physicians and Patients Should Question

### 6 Don't prescribe cholinesterase inhibitors for dementia without periodic assessment for perceived cognitive benefits and adverse gastrointestinal effects.

In randomized controlled trials, some patients with mild-to-moderate and moderate-to-severe Alzheimer's disease (AD) achieve modest benefits in delaying cognitive and functional decline and decreasing neuropsychiatric symptoms. The impact of cholinesterase inhibitors on institutionalization, quality of life and caregiver burden are less well established. Clinicians, caregivers and patients should discuss cognitive, functional and behavioral goals of treatment prior to beginning a trial of cholinesterase inhibitors. Advance care planning, patient and caregiver education about dementia, diet and exercise and non-pharmacologic approaches to behavioral issues are integral to the care of patients with dementia, and should be included in the treatment plan in addition to any consideration of a trial of cholinesterase inhibitors. If goals of treatment are not attained after a reasonable trial (e.g., 12 weeks), then consider discontinuing the medication. Benefits beyond a year have not been investigated and the risks and benefits of long-term therapy have not been well-established.

### 7 Don't recommend screening for breast or colorectal cancer, nor prostate cancer (with the PSA test) without considering life expectancy and the risks of testing, overdiagnosis and overtreatment.

Cancer screening is associated with short-term risks, including complications from testing, overdiagnosis and treatment of tumors that would not have led to symptoms. For prostate cancer, 1,055 men would need to be screened and 37 would need to be treated to avoid one death in 11 years. For breast and colorectal cancer, 1,000 patients would need to be screened to prevent one death in 10 years. For patients with a life expectancy under 10 years, screening for these three cancers exposes them to immediate harms with little chance of benefit.

### 8 Avoid using prescription appetite stimulants or high-calorie supplements for treatment of anorexia or cachexia in older adults; instead, optimize social supports, provide feeding assistance and clarify patient goals and expectations.

Unintentional weight loss is a common problem for medically ill or frail elderly. Although high-calorie supplements increase weight in older people, there is no evidence that they affect other important clinical outcomes, such as quality of life, mood, functional status or survival. Use of megestrol acetate results in minimal improvements in appetite and weight gain, no improvement in quality of life or survival, and increased risk of thrombotic events, fluid retention and death. In patients who take megestrol acetate, one in 12 will have an increase in weight and one in 23 will die. The 2012 AGS Beers criteria lists megestrol acetate and cyproheptadine as medications to avoid in older adults. Systematic reviews of cannabinoids, dietary polyunsaturated fatty acids (DHA and EPA), thalidomide and anabolic steroids, have not identified adequate evidence for the efficacy and safety of these agents for weight gain. Mirtazapine is likely to cause weight gain or increased appetite when used to treat depression, but there is little evidence to support its use to promote appetite and weight gain in the absence of depression.

### 9 Don't prescribe a medication without conducting a drug regimen review.

Older patients disproportionately use more prescription and non-prescription drugs than other populations, increasing the risk for side effects and inappropriate prescribing. Polypharmacy may lead to diminished adherence, adverse drug reactions and increased risk of cognitive impairment, falls and functional decline. Medication review identifies high-risk medications, drug interactions and those continued beyond their indication. Additionally, medication review elucidates unnecessary medications and underuse of medications, and may reduce medication burden. Annual review of medications is an indicator for quality prescribing in vulnerable elderly.

### 10 Avoid physical restraints to manage behavioral symptoms of hospitalized older adults with delirium.

Persons with delirium may display behaviors that risk injury or interference with treatment. There is little evidence to support the effectiveness of physical restraints in these situations. Physical restraints can lead to serious injury or death and may worsen agitation and delirium. Effective alternatives include strategies to prevent and treat delirium, identification and management of conditions causing patient discomfort, environmental modifications to promote orientation and effective sleep-wake cycles, frequent family contact and supportive interaction with staff. Nursing educational initiatives and innovative models of practice have been shown to be effective in implementing a restraint-free approach to patients with delirium. This approach includes continuous observation; trying re-orientation once, and if not effective, not continuing; observing behavior to obtain clues about patients' needs; discontinuing and/or hiding unnecessary medical monitoring devices or IVs; and avoiding short-term memory questions to limit patient agitation. Pharmacological interventions are occasionally utilized after evaluation by a medical provider at the bedside, if a patient presents harm to him or herself or others. Physical restraints should only be used as a very last resort and should be discontinued at the earliest possible time.

These items are provided solely for informational purposes and are not intended as a substitute for consultation with a medical professional. Patients with any specific questions about the items on this list or their individual situation should consult their physician.

## How This List Was Created (1-5)

The American Geriatrics Society (AGS) established a work group chaired by the Vice Chair of Clinical Practice and Models of Care Committee (CPMC). Work group members were drawn from that committee, as well as the Ethics, Ethnogeriatrics and Quality and Performance Measurement (QPMC) committees. AGS members were invited to submit feedback and recommendations as to what they thought should be included in the list via an electronic survey. The workgroup first narrowed the list down to the top 10 potential tests or procedures. The workgroup then reviewed the evidence and sought expert advice to further refine the list to five recommendations, which were then reviewed and approved by the AGS Executive Committee and the Chairs/Vice Chairs of CPMC, Ethics and QPMC.

## How This List Was Created (6-10)

The American Geriatrics Society (AGS) used the same work group from its first list to develop its second list. The group was chaired by the Chair of Clinical Practice and Models of Care Committee (CPMC). Work group members were drawn from that committee, as well as the Ethics, Ethnogeriatrics and Quality and Performance Measurement (QPMC) committees. AGS members were invited to submit feedback and recommendations as to what they thought should be included in a *Choosing Wisely*® list via an electronic survey. The workgroup then narrowed the list down and reviewed the evidence, seeking expert advice to further refine the list to five recommendations, which were then reviewed and approved by the AGS Executive Committee and the Chairs/Vice Chairs of CPMC, Ethics and QPMC.

AGS' disclosure and conflict of interest policy can be found at [www.americangeriatrics.org](http://www.americangeriatrics.org).

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### About the ABIM Foundation

The mission of the ABIM Foundation is to advance medical professionalism to improve the health care system. We achieve this by collaborating with physicians and physician leaders, medical trainees, health care delivery systems, payers, policymakers, consumer organizations and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice.



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### About the American Geriatrics Society

The American Geriatrics Society (AGS) works to improve the health, independence and quality of life of all older people. Our geriatrics health professional members work together to provide interdisciplinary, patient- and family-centered team care to older adults. The society also works to bring the knowledge and expertise of geriatrics health professionals to the public via [www.healthimaging.org](http://www.healthimaging.org).



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