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FridayFocus

High Risk Medication Formulary Changes for Medicare Members

Medicare has established various quality measures, one of which is evaluating use of high risk medications (HRM) in the elderly. The HRM measure contributes to a Medicare plan's overall Star Rating and assesses the percentage of Medicare beneficiaries 65 years of age or older who receive two or more prescription fills of at least one high risk medication.

The American Geriatrics Society (AGS) updated the Beers Criteria in 2015 which identifies high risk medications in older adults. These medications are associated with poor patient outcomes such as adverse drug events, hospitalizations, and mortality due to physiological changes with aging. HRMs typically have limited effectiveness in the elderly, are frequently unsafe, and risks associated with these medications are thought to outweigh the potential benefits.[1] The Medicare HRM measure applies the AGS recommendations and was adapted from measures developed and endorsed by the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF).[2]

Although a patient may tolerate a HRM currently, that patient is still vulnerable to experiencing dangerous adverse effects, especially as the patient continues to age and physiological changes occur. Discontinuation of a HRM before a safety issue arises is key in preventing patient harm.

Effective 1/1/2016, the following changes will occur on the SWHP Medicare Part D formularies which will impact SeniorCare and Vital Traditions members:

- Cyclobenzaprine and metaxalone will be removed from formulary
- Prior authorization (PA) required for carisoprodol, chlorzoxazone, methocarbamol and orphenadrine
- PA for new starts for amitriptyline, imipramine, doxepin, clomipramine and trimipramine

Attached is a listing of common high risk medications. Please carefully consider formulary alternatives, non-pharmacologic therapy, and your clinical judgment to help reduce use of these medications in the elderly.

As always, we appreciate your ideas and feedback. Thank you for the quality work you do. All *Friday Focus* editions may be found at the SWHP website: https://swhp.org/about/us/news/newsletters/providers-friday-focus.

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References:

1. The American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. published online 20 OCT 2015 | DOI: 10.1111/jgs.13919.
2. Centers for Medicare and Medicaid Services (CMS). (Sep 2014). Patient Safety Analysis: High Risk Medication Measures PDP/MA-PD Contacts Report User Guide. Burlingame, CA. 1-23.

Common High Risk Medications in the Elderly (Age≥65) and Suggested Alternatives

The medications listed below reflect common High Risk Medications (HRM), developed and endorsed by the Pharmacy Quality Alliance (PQA) in June 2012. The safer treatment options provided represent potential alternatives to HRMs. Providers should evaluate whether these alternatives can be used in place of HRMs for their patients.

Therapeutic Class	High Risk Medications	Potential Risks	Safer Treatment Options
Sedative Hypnotics	Greater than 90 days cumulative supply during plan year: • Zolpidem (Ambien, Ambien CR) • Eszopiclone (Lunesta) • Zaleplon (Sonata)	Cognitive impairment, delirium, unsteady gait, syncope, falls, motor vehicle accidents, minimal benefit	• Consider non-pharmacologic interventions, focusing on proper sleep hygiene. When sedative hypnotic medications are deemed clinically necessary, use should be at the lowest possible dose for the shortest possible time. • Trazodone (low dose) • Silenor (Quantity Limit #30/30 days) • Rozerem (Quantity Limit #30/30 days)
Skeletal Muscle Relaxants	• Carisoprodol (Soma) • Cyclobenzaprine (Flexeril) • Methocarbamol (Robaxin) • Orphenadrine (Norflex) • Metaxalone (Skelaxin) • Chlorzoxazone (Parafon Forte) • All combination products containing one of these medications	Most muscle relaxants are poorly tolerated by elderly patients due to anticholinergic adverse effects, sedation, fall risk, delirium, and weakness. At doses tolerated by elderly patients, their effectiveness is questionable.	• Consider non-pharmacologic treatments, such as cryotherapy, heat, massage and stretching/exercise. • Baclofen • Tizanidine tablets
Tertiary Amine Tricyclic Antidepressants (TCAs)	• Amitriptyline • Clomipramine • Doxepin (>6 mg/day) • Imipramine • Trimipramine	Strong anticholinergic effects (dry mouth, constipation, vision disturbances), sedation, increased risk for falls	**For Depression / Anxiety / OCD:** • Secondary Amine TCAs (Nortriptyline, Protriptyline, Desipramine, Amoxapine) • SSRIs (Fluoxetine, Citalopram, Paroxetine, Sertraline) • SNRIs (Venlafaxine, Duloxetine) • Bupropion **For neuropathic pain / fibromyalgia:** Gabapentin, Duloxetine, Lyrica **For prevention of migraine:** Propranolol, Divalproex sodium, Topiramate
Oral Hypoglycemics	• Glyburide (Diabeta) • Chlorpropamide (Diabinese)	Greater risk of severe, prolonged hypoglycemia	• Glimepiride • Glipizide

Common High Risk Medications in the Elderly (Age≥65) and Suggested Alternatives

Urinary Anti-Infectives	Greater than 90 days cumulative supply during the plan year: • Nitrofurantoin (Furadantin) • Nitrofurantoin monohydrate/ macrocrystals (Macrobid) • Nitrofurantoin macrocrystals (Macrodantin)	Associated with an increased risk of pulmonary toxicity, neuropathy and hepatotoxicity when renal function is decreased. Also, less effective when CrCl<60 mL/min.	**For prevention of recurrent UTIs:** • TMP-SMX • Fluoroquinolones • Beta-lactam antibiotics • Optimal dose, frequency and duration are not known • Consider antibiotic resistance patterns and patient antibiotic history
Cardiovascular	• Digoxin (>0.125 mg/day)	In heart failure, higher dosages associated with no additional benefit and may increase risk. Decreased renal clearance may increase risk of toxicity.	Dose reduction (≤0.125mg/day)
Estrogens and Estrogen / Progesterone Products (Oral and Transdermal)	• Conjugated estrogen (Premarin) • Conjugated estrogen / medroxy-progesterone (Prempro, Premphase) • Estradiol, oral (Estrace, Femtrace) • Estradiol patch (Alora, Climara, Estraderm, Estradiol, Menostar, Vivelle-Dot) • Estradiol / drospirenone (Angeliq) • Estradiol / levonorgestrel (ClimaraPro) • Estradiol / norethindrone (CombiPatch) • Estradiol / norgestimate (Prefest) • Estropipate (Ogen, Ortho-Est) • Esterified estrogen (Menest) • Esterified estrogen / methyltestosterone (Covaryx, Estratest) • Ethinyl estradiol / norethindrone (Activella, FemHRT)	Elderly patients on long-term oral estrogens are at increased risk for breast and endometrial cancer. In addition, results from the Women's Health Initiative (WHI) hormone trial suggest these medications may increase the risk of heart attack, stroke, blood clots, and dementia.	**For Hot Flashes:** Continuously re-evaluate the need for long-term estrogen therapy; evaluate non-drug therapy. Postmenopausal women should avoid using oral estrogens for more than 3 years. After 3 years patients should be titrated off therapy due to the risks outweighing the benefits. Consider the following alternatives: • Brisdelle • SSRIs, Gabapentin, and Venlafaxine have non-FDA labeled indications (medically accepted use) for hot flashes. **For Vaginal Symptoms:** Premarin Cream **For Bone Density:** • Alendronate • Actonel (risedronate) • Evista (raloxifene)

References:

1. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. JAGS. 2012; 60: 616-31.
2. PQA. Use of High-Risk Medications in the Elderly: Review and Revision of Performance Measure. June 2012.