APPENDIX III:
Potentially Inappropriate Medications and Medicare Part D Coverage

Part D Exclusion Category	Potentially Inappropriate Medications	Rationale for PIM Classification
Agents when used for anorexia, weight loss or weight gain.	Amphetamines and anorexic agents, including: dextroamphetamine, methamphetamine, and methylphenidate.	Amphetamines and anorexic agents may cause dependence, hypertension, angina, and myocardial infarction. May suppress appetite in patients with anorexia or malnutrition, and have CNS-altering effects in patients with underlying cognitive impairment.
Agents when used for the symptomatic relief of cough and colds.	Antihistamines (chlorpheniramine and diphenhydramine).	All non-prescription and many prescription antihistamines may have potent anticholinergic properties. Antihistamines without anticholinergic effects are preferred in elderly patients.
	Decongestants when used in patients with bladder flow obstruction.	May decrease urinary flow, leading to urinary retention.
Barbiturates (except Phenobarbital)	All barbiturates, except when used to control seizures.	Barbiturates are highly addictive and cause more adverse effects than other sedative or hypnotic drugs in elderly patients.
Benzodiazepines	Short-acting benzodiazepines: doses greater than lorazepam 3mg, oxazepam 60mg, alprazolam 2mg, temazepam 15mg and triazolam 0.25mg.	Because of increased sensitivity to benzodiazepines in elderly patients, smaller doses may be effective as well as safer. Total daily doses should rarely exceed the suggested maximums.
	Long-acting benzodiazepines: chlordiazepoxide, diazepam, quazepam, halazepam, and chlorazepate.	These drugs have a long half-life in elderly patients (often several days), producing prolonged sedation and increasing the risk of falls and fractures.
	Flurazepam (Dalmane).	This benzodiazepine hypnotic has an extremely long half-life in elderly patients (often days), producing prolonged sedation and increasing incidence of falls and fracture. Medium- or short-acting benzodiazepines are preferable.
	Long acting benzodiazepines in patients with stress incontinence.	May cause polyuria and worsening of incontinence.
	Short- to intermediate-acting benzodiazepines used in patients with syncope or falls.	May produce ataxia, impaired psychomotor function, syncope, and additional falls.
	Long-acting benzodiazepines used in patients with COPD.	CNS adverse effects. May induce respiratory depression. May exacerbate or cause respiratory distress.

Part D Exclusion Category	Potentially Inappropriate Medications	Rationale for PIM Classification
Nonprescription drugs	Anticholinergics and antihistamines: chlorpheniramine and diphenhydramine.	All non-prescription and many prescription antihistamines may have potent anticholinergic properties. Antihistamines without anticholinergic effects are preferred in elderly patients.
	Diphenhydramine (Benadryl).	May cause confusion and sedation. Should not be used as a hypnotic. The smallest possible dose should be used for the treatment of anaphylactic reactions.
	Ferrous sulfate>325 mg/d.	Doses>325 mg/d do not dramatically increase the amount absorbed but greatly increase the incidence of constipation.
	Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs, such as naproxen.	Have a potential to produce GI bleeding, renal failure, high blood pressure, and heart failure.
	Long term use of stimulant laxatives, such as bisacodyl and cascara sagrada, except in the presence of opiate analgesic use.	May exacerbate bowel dysfunction.
	Mineral oil.	Potential for aspiration and adverse effects. Safer alternatives available.
	Cimetidine (Tagamet).	CNS adverse effects including confusion.
	Decongestants used in patients with bladder flow obstruction.	May decrease urinary flow, leading to urinary retention.
	Decongestants used in patients with insomnia.	Concern due to CNS stimulant effects.
	Pseudoephedrine and diet pills used in patients with hypertension.	May produce elevation of blood pressure secondary to sympathomimetic activity.
	NSAIDs and aspirin (>325 mg), coxibs excluded, used in patients with gastric or duodenal ulcers.	May exacerbate existing ulcers or produce new/additional ulcers.
	Aspirin and NSAIDs used in patients with blood clotting disorders or receiving anticoagulant therapy.	May prolong clotting time, elevate INR values or inhibit platelet aggregation, resulting in an increased potential for bleeding.
Propoxyphene and combination products	Offers few analgesic advantages over acetaminophen, yet has the adverse effects of other narcotic drugs.	These medications are considered potentially inappropriate in elderly patients. Formulary alternatives include oxycodone/APAP and hydrocodone/APAP, as well as more potent single ingredient opioids.
Indomethacin	Of all available nonsteroidal anti-inflammatory drugs, this drug produces the most CNS adverse effects.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include non-steroidal anti-inflammatory drugs with the lowest risk of gastrointestinal toxicity, including celecoxib, etodolac, ibuprofen, and nabumetone.
Pentazocine	Narcotic analgesic that causes more CNS adverse effects, including confusion and hallucinations, more commonly than other narcotic drugs. Additionally, it is a mixed agonist and antagonist.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include full opioid agonists such as oxycodone/APAP and hydrocodone/APAP, as well as more potent single ingredient opioids.

Potentially Inappropriate Medications Covered Under Medicare Part D		
Drug	**Concern**	**Risks and Implications for Part D**
Muscle relaxants and anti-spasmodics: methocarbamol, carisoprodol, chlorzoxazone, metaxalone, cyclobenzaprine, orphenadrine, oxybutynin (excluding extended-release oxybutynin).	Most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients due to anticholinergic adverse effects. Their effectiveness at doses tolerated by elderly patients is questionable.	These medications are considered potentially inappropriate in elderly patients. There are limited pharmacological alternatives that do not present similar risks for elderly patients.
Amitriptyline, chlordiazepox-ide-amitriptyline, per-phenazine-amitriptyline	Because of its strong anticholinergic and sedation properties, amitriptyline is rarely the antidepressant of choice for elderly patients.	These medications are considered potentially inappropriate in elderly patients. Formulary alternatives include selective serotonin reuptake inhibitors (SSRI) with a lower risk of drug interactions and side effects, such as sertraline, citalopram and escitalopram.
Doxepin	Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for elderly patients.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include SSRIs with a lower risk of drug interactions and side effects, such as sertraline, citalopram and escitalopram.
Meprobamate	This is a highly addictive and sedating anxiolytic. Patients using meprobamate for prolonged periods may become addicted and may need to be withdrawn slowly.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include buspirone. Several SSRIs and SSRI-like medications are also available with anxiety indications.
Disopyramide	Of all antiarrhythmic drugs, this is the most potent negative inotrope and therefore may induce heart failure in elderly patients. It is also strongly anticholinergic. Other antiarrhythmic drugs should be used.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives include quinidine and procainamide.
Digoxin (should not exceed >0.125 mg/d except when treating atrial arrhythmias)	Decreased renal clearance may lead to increased risk of toxic effects.	This medication is considered potentially inappropriate in elderly patients. Patients who suffer from congestive heart failure and need digoxin reduction in hospitalization rates and increased exercise tolerance should not exceed the recommended dose.
Short-acting dipyridamole. Do not consider the long-acting dipyridamole, which has better properties than the short-acting in older adults, except with patients with artificial heart valves.	May cause orthostatic hypertension.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include clopidogrel.
Methyldopa and methyldopa-hydrochlorothiazide	May cause bradycardia and exacerbate depression in elderly patients.	This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.

Potentially Inappropriate Medications Covered Under Medicare Part D		
Drug	**Concern**	**Risks and Implications for Part D**
Reserpine at doses >0.25 mg	May induce depression, impotence, s edation and orthostatic hypotension.	This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.
Chlorpropamide	It has a prolonged half-life in elderly patients and could cause prolonged hypoglycemia. Additionally, it is the only oral hypoglycemic agent that causes SIADH.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include second generation sulfonylureas with a lower risk of prolonged hypoglycemia, such as glyburide, glipizide and glimepiride.
Gastrointestinal antispasmodic drugs: dicyclomine, hyoscyamine, propantheline, belladonna alkaloids, clidinium-chlordiazepoxide	GI antispasmodic drugs are highly anticholinergic and have uncertain effectiveness. These drugs should be avoided (especially for long-term use).	These medications are considered potentially inappropriate in elderly patients. There are limited alternatives for this class of agents.
Anticholinergics and antihistamines: hydroxyzine, cyproheptadine, promethazine, triplennamine, dexchlorpheniramine	All nonprescription and many prescription antihistamines may have potent anticholineric properties. Nonanti-cholinergic antihistamines are preferred in elderly patients when treating allergic reactions.	These medications are considered potentially inappropriate in elderly patients. Formulary alternatives should include agents from the nonsedating antihistamine class, such as cetirizine, desloratadine and fexofenadine.
Ergot mesyloids and cyclandelate	Have not been shown to be effective in the doses studied.	These medications are considered potentially inappropriate in elderly patients. Cyclandelate is no longer widely available. Formulary alternatives to ergot mesyloids include triptan agents (e.g., sumatriptan, eletriptan) and long-term preventative therapy for patients with chronic migraine concerns (e.g., beta-blockers, calcium channel blockers, anticonvulsants).
Meperidine	Not an effective oral analgesic in doses commonly used. May cause confusion and has many disadvantages to other narcotic drugs.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include other potent opioids such as morphine, hydromorphone and oxycodone.
Ticlopidine	Has been shown to be no better than aspirin in preventing clotting and may be considerably more toxic. Safer, more effective alternatives available.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include clopidogrel.
Ketorolac	Immediate and long-term use should be avoided in older persons, since a significant number have asymptomatic GI pathological conditions.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include nonsteroidal anti-inflammatory drugs with the lowest risk of gastrointestinal toxicity, including celecoxib, etodolac, ibuprofen and nabumetone.
Daily fluoxetine	Long half-life of drug and risk of producing excessive CNS stimulation, sleep disturbances, and increasing agitation. Safer alternatives available.	This medication is considered potentially inappropriate in elderly patients. Physicians should consider every-other-day dosing or SSRIs with shorter half-lives, such as citalopram and escitalopram.

Potentially Inappropriate Medications Covered Under Medicare Part D		
Drug	**Concern**	**Risks and Implications for Part D**
Amiodarone	Associated with QT interval problems and risk of provoking torsades de pointes. Lack of efficacy in older adults.	This medication is considered potentially inappropriate in elderly patients. Cardioversion or nonpharmacological therapy may be necessary.
Guanethidine	May cause orthostatic hypotension. Safer alternatives available.	This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.
Guanadrel	May cause orthostatic hypotension.	This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.
Isoxsuprine	Lack of efficacy.	This medication is considered potentially inappropriate in elderly patients. There is limited availability of this product and utilization is unlikely.
Nitrofurantoin	Potential for renal impairment. Safer alternatives available.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives for urinary tract infections should include ciprofloxacin and sulfamethoxazole-trimethoprim.
Doxazosin	Potential for hypotension, dry mouth and urinary problems.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives for hypertension should include diuretics, beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers. Formulary alternatives for benign prostatic hyperplasia should include agents that specifically target alpha receptors in the prostate, such as tamsulosin.
Methyltestosterone	Potential for hypertrophy and cardiac problems.	Only a small subset of individuals with longstanding androgenic concerns would be subject to exposure to this drug. Topical androgen applications may present safer alternatives.
Thioridazine	Greater potential for CNS and extrapyramidal adverse effects.	This medication is considered potentially inappropriate in elderly patients. First-generation antipsychotics are not agents of first choice because of their extensive side-effect profile, including potent anticholinergic effects. Formulary alternatives should include aripiprazole, olanzapine, quetiapine, risperidone and ziprasidone.
Mesoridazine	CNS and extrapyramidal adverse effects.	This medication is considered potentially inappropriate in elderly patients. First-generation antipsychotics are not agents of first choice because of their extensive side-effect profile, including potent anticholinergic effects. Formulary alternatives should include aripiprazole, olanzapine, quetiapine, risperidone and ziprasidone.
Short-acting nifedipine	Potential for hypotension and constipation.	This medication is considered potentially inappropriate in elderly patients. The use of short-acting dihydropyridine calcium channel blockers is no longer recommended. The long-acting formulation of nifedipine is an acceptable alternative.
Clonidine	Potential for orthostatic hypotension and CNS adverse effects.	This medication is considered potentially inappropriate in elderly patients. Due to the multitude of antihypertensives currently available, there is limited utility for this older antihypertensive.

Potentially Inappropriate Medications Covered Under Medicare Part D		
Drug	**Concern**	**Risks and Implications for Part D**
Ethacrynic acid	Potential for hypertension and fluid imbalances. Safer alternatives available.	This medication is considered potentially inappropriate in elderly patients. The use of this loop diuretic is predominantly limited to patients with a sulfonamide allergy. Formulary alternatives for patients without a sulfonamide allergy include bumetanide, furosemide and torsemide.
Desiccated thyroid	Concerns about cardiac effects. Safer alternatives available.	This medication is considered potentially inappropriate in elderly patients. Formulary alternatives should include levothyroxine formulations.
Amphetamines (excluding methylphenidate hydrochloride and anorexics).	CNS stimulant adverse effects.	These medications are considered potentially inappropriate in elderly patients. There is limited demand for these agents in an elderly population. If necessary, formulary alternatives should include methylphenidate formulations.
Estrogens only (oral)	Evidence of the carcinogenic (breast and endometrial cancer) potential of these agents and lack of cardio-protective effect in older women.	These medications are considered potentially inappropriate in elderly patients. Estrogenic agents should only be used during the perimenopausal period to aid in relief of menopausal symptoms. Long-term prevention or treatment of osteoporosis should be managed with formulary alternatives including calcitonin or bisphosphonates.