

F329 Unnecessary Medications Table 1 Medication Issues of Particular Relevance

This document was prepared based on guidance available as of November 20, 2006.

F-329 Unnecessary Medications Table 1
Medication Issues of Particular Relevance

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
A	<u>Analgesics</u> Acetaminophen	Not included in old guidelines	Dosage should not be greater than 4gm daily.	<ol style="list-style-type: none"> 1. Monitor dosage an usage of greater than 4 gm per day. 2. Yearly LFT's.
B	NSAID's and COX II's	Not included in old guidelines	Indications – inflammatory conditions Interactions with Aspirin Adverse Events – GI bleed, worsening renal function, and CNS side effects	<ol style="list-style-type: none"> 1. Monitor for GI bleed if given (especially with ASA). 2. Renal function minimum yearly if given on a scheduled dosage.
C	Opioid Analgesics	Meperidine is mentioned as medications that is not appropriate in the elderly.	Indication - Long Acting Opioids should not be started unless shorter acting agents have failed or titration of shorter agents has been established.	<ol style="list-style-type: none"> 1. Monitor for constipation in the elderly receiving opioid analgesics. 2. Monitor for signs of confusion and possible seizures, if meperidine is used. Or recommend alternative therapy.
D	Pentazocine	Listed as an agent with a high potential for severe adverse events in the elderly	Not recommended for use in the elderly population.	<ol style="list-style-type: none"> 1. Recommended alternative therapy. Monitor for CNS side effects if pentazocine is continued.
E	Propoxyphene	Beers medication	Not recommended for use in the elderly population. Few benefits over acetaminophen.	<ol style="list-style-type: none"> 1. Recommend alternative therapy. Monitor for CNS side effects if propoxyphene is continued.
F	<u>Antibiotics</u> All Antibiotics	Not included in old guidelines	Use should be limited to confirmed or suspected bacterial infections.	<ol style="list-style-type: none"> 1. Monitor for signs and symptoms of allergic reaction. 2. Monitor for secondary infections like <i>C. difficile</i> colitis, thrush, and vaginitis. 3. Monitor for GI side effects like diarrhea.
G	Aminoglycosides and Vancomycin	Not included in old guidelines	Use should be limited to confirmed or suspected bacterial infections.	<ol style="list-style-type: none"> 1. Monitor renal function. 2. Monitor for signs of ototoxicity.
H	Nitrofurantoin	Not included in old guidelines	It is not the drug of choice for UTI's or prophylaxis of UTI's for patients with a GFR of less than 60 ml/min.	<ol style="list-style-type: none"> 1. Monitor renal function prior to initiation of therapy. 2. Monitor pulmonary function tests and for peripheral neuropathy if administered long-term.
I	Fluoroquinolones	Not included in old guidelines	Should be avoided with patients with prolonged QTc intervals or in patients on antiarrhythmic agents. May affect glucose control in the elderly if on quinolones and have impaired renal function.	<ol style="list-style-type: none"> 1. Monitor renal function prior to initiation of therapy. 2. For diabetic patients – monitor blood glucose.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
J	<u>Anticoagulants</u> Warfarin	Appropriate monitoring of INR	Use must be monitored by PT/INR with frequency determined by clinical circumstances, duration of use and stability of monitoring results. See F428 for Table of Common Medication Interactions in LTC that significantly increase PT/INR results to ranges associated with life-threatening bleeding, or decrease PT/INR results to ineffective ranges, or increase or decrease the serum concentration of the interacting drug.	<ol style="list-style-type: none"> 1. Frequent monitoring of INR while on warfarin, particularly with initiation of therapy. 2. Assessment of INR that does not fall within the desired range for therapy. 3. Monitor potential drug-drug and food-drug interactions that may occur with warfarin.
K	<u>Anticonvulsants</u> All anticonvulsants	Appropriate monitoring of serum concentrations for agents with a narrow therapeutic index.	<p>Anticonvulsants may be used to treat bipolar disorder, schizoaffective disorder, neuropathic pain, and migraine headache prophylaxis as well as seizures.</p> <p>Determination of seizure type and distinguish if it is an isolated incident.</p> <p>Gradual Dosage reductions guidance must be followed if used to manage behaviors.</p>	<ol style="list-style-type: none"> 1. Appropriate serum concentration monitoring of respective anticonvulsants at initiation of therapy (after steady state) and every 6 months thereafter for treatment of seizures. Serum concentration monitoring is appropriate for: phenytoin, phenobarbital, primidone, valproic acid, and carbamazepine. 2. Appropriate monitoring of LFT's and CBC's yearly. 3. Monitor for signs of toxicity, particularly the agents that may increase the risk for falls.
L	<u>Antidepressants</u> All Antidepressant Classes	<ol style="list-style-type: none"> 1. Diagnosis and Treatment of Depression in the elderly. 2. Mention of agents like amitriptyline, doxepin, phenelzine, and tranylcypromine as agents not being the drug of choice in the elderly. 	<p>Agents are indicated to treat depression as defined.</p> <p>Class may be used to treat anxiety disorders, post - traumatic stress disorder, OCD, insomnia, neuropathic pain, insomnia, and migraine headaches.</p> <p>Assess the risk versus benefit of using 2 or more antidepressants.</p> <p>Duration of therapy consistent with treatment guidelines.</p> <p>Prior to discontinuing the medication, a tapering protocol or gradual dosage reduction to avoid withdrawal syndrome.</p> <p>If used to manage behavior, stabilize mood, insomnia, or psychiatric disorder must comply with gradual dose reduction guidelines.</p>	<ol style="list-style-type: none"> 1. Monitor for efficacy of the medication and / or worsening of the disease state. 2. Monitor for side effects especially if the agent increases risks for falls. 3. Monitor for seizure risk if on bupropion. 4. Monitor drug - drug interactions (SSRI's). 5. Where appropriate, monitor for SIADH and signs of serotonin syndrome.
M	Monoamine Oxidase Inhibitors	Mentioned as an antidepressant drug class that is not the drug of choice in the elderly.	Not indicated if patient has CVA , HTN, or cardiovascular disease. Also avoid in patients with pheochromocytoma.	<ol style="list-style-type: none"> 1. Monitor for anticholinergic side effects. 2. Monitor vital signs.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
N	Tricyclic Antidepressants	Mentioned as an antidepressant drug class that is not the drug of choice in the elderly.	Rarely the drug of choice due to strong anticholinergic and sedation properties. Exceptions are in patients with neuropathic pain	1. Monitor for anticholinergic side effects. 2. Monitor for sedation, orthostasis and falls.
O	<u>Antidiabetic Agents</u> Insulin, Oral hypoglycemics, Combination Products, and Inhaled Insulin	Not included in old guidelines	Use of antidiabetic medications should include monitoring for effectiveness based on desired goals for that individual and to identify complications of treatment such as hypoglycemia, impaired renal function. Residents on rosiglitazone should be monitored for visual deterioration due to new onset and/or worsening of macular edema in diabetic patients. Metformin has been associated with development of lactic acidosis which is more likely to occur with elevated serum creatinine, abnormal creatinine clearance, age > 80 years, radiologic studies with iodinated contrast dyes, congestive heart failure requiring pharmacologic management, acute or chronic metabolic acidosis with or without coma. Rosiglitazone and pioglitazone have been associated with edema and weight gain and should be avoided in residents with Stage III or IV heart failure. Sulfonylureas can cause SIADH.	1. Monitoring for efficacy to meet desired goals of treatment. Fasting Blood Sugars (Q 60 days) or hemoglobin A1c (Q 90 or 120 days) is desired. 2. Monitor for signs of complication (hypoglycemia), and symptoms of long uncontrolled diabetes (renal function, neuropathy, eye exams) 3. Eye exams for new starts of rosiglitazone. 4. Renal function for patients being initiated or maintained on metformin. 5. Symptoms of worsening CHF for diabetics on rosiglitazone or pioglitazone. 6. Serum sodium concentration monitoring for patients on sulfonylureas.
P	Chlorpropamide and Glyburide	Mentioned as an medication that is not ideal in the elderly due to a long half life and an increased risk for hypoglycemia.	Glyburide added to chlorpropamide as potentially unnecessary. Both drugs have long half-lives and increased risks for hypoglycemia in older persons.	1. Alternative antidiabetic agents are recommended. 2. If continued, monitor for signs of hypoglycemia.
Q	<u>Antifungals</u> Imidazoles	Not included in old guidelines	Appropriate indication to be used for lowest effective dose and stop dates.	1. Monitor labs more closely with medications that have significant drug-drug interactions with antifungals. (i.e., warfarin, theophylline, phenytoin, and sulfonylureas). 2. Monitor LFT's (side effects).

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
R	<u>Antimanic Medications</u> Lithium	Appropriate monitoring of levels	Should be avoided in patients with electrolyte abnormalities (sodium depletion) Should be avoided in patients with significant renal and cardiovascular disease.	<ol style="list-style-type: none"> 1. Monitor lithium serum concentrations every 6 months. 2. Concurrent monitoring of electrolytes and thyroid function tests every six months. 3. Monitor for drug interactions with NSAID's, diuretics, and ACE inhibitors.
S	<u>Antiparkinson Medications</u> COMT inhibitors, Dopamine agonists, MAO inhibitors, and combinations	Not included in old guidelines with the exception of the language for MAO inhibitors	<p>May cause significant confusion, restlessness, delirium, dyskinesia, nausea, dizziness, hallucination, and agitation.</p> <p>Increased risk of postural hypotension and falls, especially when given with antihypertensive medications.</p>	<ol style="list-style-type: none"> 1. Monitor for side effects, especially the side effects that may increase the risk for falls and fractures (confusion, dizziness, postural hypotension, hallucinations, agitation, and delirium). 2. Monitor blood pressure carefully in residents receiving antiparkinson and antihypertensive medications concomitantly.
T	<u>Antipsychotics</u>	<p>Indications schizophrenia schizo-affective disorder delusional disorder psychotic mood disorders (mania/ depression with psychotic features) acute psychotic episodes brief reactive psychosis schizophreniform disorder Atypical psychosis</p> <p>OMS (delirium, dementia, amnestic and other cognitive disorders with associated psychotic illness or delirium)</p> <p>Tourette's disorder</p> <p>Huntington's disorder</p>	<p>Indications schizophrenia schizo-affective disorder delusional disorder mood disorders (mania, bipolar, depression with psychotic features, refractory major depression) atypical psychosis psychosis NOS schizophreniform disorder brief psychotic disorder</p> <p>dementing illnesses with associated behavior symptoms</p> <p>Medical illness or delirium with manic or psychotic symptoms and/or therapy related psychosis or mania (e.g., thyrotoxicosis, neoplasms, high dose steroids)</p>	

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
U	<u>Antipsychotics</u> (continued)		<p>Criteria Diagnosis alone does not warrant use of antipsychotics-clinical condition must also meet the following criteria: A. symptoms are identified as mania or psychosis B. symptoms present danger to self or others C. symptoms are significant enough that resident is experiencing one of the following: inconsolable or persistent distress (fear, continuous yelling, screaming, distress with end of life, or crying) or significant decline in function; and/or substantial difficulty receiving needed care (not eating resulting in weight loss, fear, and not bathing leading to skin breakdown or infection).</p>	Criteria to support antipsychotic use must be documented clearly in the medical record.
V	<u>Antipsychotics</u> (continued)	<p>Additional Requirements</p> <p>Behavior must be quantitatively and objectively documented to assist in: assessing need for intervention, determining whether behavior is transitory or permanent, relating behavior to other events in the resident's life, ruling out environmental causes such as heat, noise, overcrowding, ruling out medical causes such as pain, constipation, fever, infection.</p>	<p>Additional Requirements</p> <p>Acute situations must meet one of the above criteria and all of the additional requirements: A. use limited to 7 days, and B. clinician in conjunction with intervention team must evaluate the situation within 7 days, and C. nonpharmacologic intervention must be attempted, unless contraindicated, and documented following the resolution of enduring psychiatric conditions (non-acute, chronic, or prolonged)</p> <p>Antipsychotics can be used if they meet criteria above AND before initiating or increasing antipsychotic for this condition, target behavior must be clearly identified and monitored objectively, and qualitatively to ensure the behavior symptoms are: A. not due to medical condition B. persistent or likely to recur without treatment, and C. not relieved by non-pharmacologic intervention, and D. not due to environmental stressors, and E. not due to psychological stressors</p> <p>After initiating or increasing the dose of an antipsychotic, the behavior symptom must be reevaluated periodically to determine the effectiveness of the medication and the potential for reducing or discontinuing the dose.</p> <p>(Exception: when used for behavioral disturbances related to Tourette's or non-psychiatric indications such as Huntington's, hiccups, nausea and vomiting associated with cancer, or adjunctive therapy at the end of life.)</p>	<p>1. Facilities will have policies and procedures to emphasize appropriate initiation and maintenance of non-pharmacologic interventions as well as policies and procedures for antipsychotic use for acute psychiatric situations.</p> <p>2. Document appropriate symptom reevaluation.</p>

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
W	<u>Antipsychotics</u> (continued)	<p><u>Inadequate Indications</u></p> <p>Antipsychotics should not be used if the only indication is one of the following:</p> <ol style="list-style-type: none"> 1. wandering 2. poor self care 3. restlessness 4. impaired memory 5. anxiety 6. insomnia 7. unsociability 8. indifference to surroundings 9. fidgeting 10. nervousness 11. uncooperativeness 12. agitated behavior which does not represent a danger to the resident or others 	<p><u>Inadequate Indications</u></p> <p>Antipsychotics should not be used if the only indication is one of the following:</p> <ol style="list-style-type: none"> 1. wandering 2. poor self care 3. restlessness 4. impaired memory 5. mild anxiety 6. insomnia 7. unsociability 8. inattention or indifference to surroundings 9. fidgeting 10. nervousness 11. uncooperativeness 12. verbal expressions or behavior that is not due to conditions above and does not represent danger to the resident or others. 	
X	<u>Antipsychotics</u> (continued)	<p><u>Dosage</u></p> <p>Acetophenazine 20mg Not included Chlorpromazine 75mg Chlorprothixene 75mg Clozapine 50mg Fluphenazine 4mg Haloperidol 4mg Loxapine 10mg Mesoridazine 25mg Molindone 10mg Olanzapine 10mg Perphenazine 8mg Not included Prochlorperazine 10mg Promazine 150mg Quetiapine 200mg Risperidone 2mg Thioridazine 75mg Trifluoperazine 8mg Triflupromazine 20mg Thiothixene 7mg Not included</p>	<p><u>Dosage</u></p> <p>No longer available Aripiprazole 10mg Chlorpromazine 75mg No longer available Clozapine 50mg Fluphenazine 4mg Haloperidol 2mg- note new dose Loxapine 10mg Loxapine 10mg No longer listed Molindone 10mg Olanzapine 7.5mg- note new dose Perphenazine 8mg Pimozide* Prochlorperazine* No longer available Quetiapine 150mg- note new dose Risperidone 2mg Thioridazine 75mg Trifluoperazine 8mg No longer available Thiothixene 7mg Ziprasidone*</p>	

*not customarily used for treatment of behavior

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
Y	<u>Antipsychotics</u> (continued)	<p>Duration</p> <p>For patients with organic mental syndrome, must attempt a GDR at least twice in one year unless deemed clinically contraindicated</p>	<p>Duration</p> <p>Within the first year a resident is admitted on an antipsychotic or initiated on an antipsychotic used to manage behavior, stabilize mood, or treat a psychiatric disorder, must undergo a GDR, in 2 separate quarters (with at least 1 month between the attempts), unless contraindicated. After the 1st year, must undergo GDR annually unless clinically contraindicated (see section V of F329).</p>	<p>GDRs now expected for all indications including schizophrenia, bipolar mania, and depression with psychotic features, etc., unless clinically contraindicated.</p>
Z	<u>Antipsychotics</u> (continued)		<p>Monitoring</p> <p>The facility must assure residents are being adequately monitored for adverse consequences. When used without adequate monitoring, they may be considered unnecessary medications.</p>	<p>1. Monitor for:</p> <ul style="list-style-type: none"> - anticholinergic effects - increased cholesterol, triglycerides - akathisia - parkinsonism - neuroleptic malignant syndrome - blood glucose - cardiac arrhythmias - orthostatic hypotension - heart-related events - cerebrovascular event (i.e. stroke, transient ischemic attack) - falls - tardive dyskinesia - lethargy - excessive sedation
ZA	<u>Anxiolytics</u> Benzodiazepines (long and short acting), buspirone, other antidepressants other than bupropion	<p>Indications</p> <p>A. Generalized Anxiety Disorder</p> <p>B. Organic Mental Syndrome</p> <p>C. Panic disorder</p> <p>D. Symptomatic anxiety with another diagnosed psychiatric disorder.</p>	<p>Indications</p> <p>A. Generalized Anxiety Disorder</p> <p>B. Panic disorder</p> <p>C. Symptomatic anxiety that occurs with another diagnosed psychiatric disorder</p> <p>D. Sleep disorders</p> <p>E. Acute alcohol or benzodiazepine withdrawal</p> <p>F. Significant anxiety due to a situational trigger</p> <p>G. Delirium, dementia, and other cognitive disorders with associated behaviors that: are quantitatively and objectively documented; are persistent; not due to preventable reasons; constitute clinically significant distress or dysfunction to resident or danger to self or others.</p>	<p>1. Document that anxiolytics are being used for one of the noted indications.</p> <p>2. Document that other possible reasons for the individual's distress have been considered.</p> <p>3. Document that use results in maintenance or improvement in the individual's mental, physical, or psychosocial well-being.</p>

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
	<u>Anxiolytics</u> (continued)	<p>Clinical Situations that may warrant their use:</p> <p>Long Acting Benzodiazepine used to withdraw from a Short Acting benzodiazepine</p> <p>Clonazepam used for bipolar disorders, tardive dyskinesia, nocturnal myoclonus or seizure disorders, diazepam for neuromuscular syndromes</p>	<p>Clinical Situations that may warrant their use:</p> <p>Long Acting Benzodiazepine used to withdraw from a Short Acting benzodiazepine</p> <p>Neuromuscular syndromes (e.g. cerebral palsy, tardive dyskinesia, restless leg syndrome or seizure disorders)</p> <p>Symptom relief for end of life situations</p>	<p>4. Document if one of the clinical situations warranting the use of anxiolytics exists.</p>
ZB	<u>Anxiolytics</u> (continued)	<p>Dosage</p> <p>Alprazolam 0.75mg Chloral hydrate 500mg Clonazepam 1.5mg Chlordiazepoxide 20mg Clorazepate 15mg Diazepam 5mg Diphenhydramine 50mg Estazolam 0.5mg Flurazepam 15mg Halazepam 40mg Hydroxyzine 50mg Lorazepam 2mg Oxazepam 30mg Quazepam 7.5mg</p>	<p>Dosage</p> <p>Alprazolam 0.75mg Chloral hydrate 500mg Clonazepam 1.5mg Chlordiazepoxide 20mg Clorazepate 15mg Diazepam 5mg Diphenhydramine 50mg Estazolam 0.5mg Flurazepam 15mg No longer available Hydroxyzine 50mg Lorazepam 2mg Oxazepam 30mg Quazepam 7.5mg</p>	
ZC	<u>Anxiolytics</u> (continued)	<p>Duration</p> <p>Daily use is less than 4 consecutive months unless an attempt at a GDR is unsuccessful.</p>	<p>Duration</p> <p>During 1st year of therapy (new order or after admission), attempt GDR during at least 2 separate quarters with at least 1 month between attempts. After 1st year attempt annually unless contraindicated (see section V, F329).</p>	<p>Antidepressants (except bupropion) if used for anxiety or other diagnosis listed in section ZA are subject to GDR requirements.</p>
ZD	<u>Diphenhydramine and Hydroxyzine</u>	<p>Not listed in regulations.</p>	<p>Not appropriate for use as anxiolytics</p>	<p>1. Recommend alternative therapy.</p>
ZE	<u>Meprobamate</u>	<p>Potentially contraindicated with COPD</p>	<p>Not indicated for use in older patients</p>	<p>1. Recommend alternative therapy.</p>

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
ZF	<u>Cardiovascular Medications</u> Amiodarone	Not listed in regulations	Only indication is to treat documented life-threatening ventricular arrhythmias that do not respond to other agents Dosage/Monitoring: critical to use the lowest possible dose for shortest possible duration	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor for drug-drug interactions (e.g. digoxin and warfarin).
ZG	Disopyramide	Potent negative inotropic effects which may induce heart failure and is strongly anticholinergic	Potent negative inotropic effects which may induce heart failure and is strongly anticholinergic.	
ZH	All Antihypertensives	Not listed in regulations.	<p>Doses may require modification in order to achieve desired effects while minimizing adverse consequences especially when multiple agents are prescribed. When discontinuing medication, gradual dosage tapering may be required.</p> <p>May cause dizziness, postural hypotension, fatigue, and increase risks for falls.</p> <p>Many medications interact with antihypertensives.</p>	<ol style="list-style-type: none"> 1. Document supporting diagnoses for multiple antihypertensives 2. Monitor blood pressure and potential adverse consequences. 3. Monitor for potential drug interactions (e.g. nitrates). 4. Monitor electrolytes and renal function.
ZI	<u>Alpha Blockers</u> (alfuzosin, doxazosin, prazosin, tamsulosin, and terazosin)	Not listed in regulations	<p>Doxazosin, prazosin and terazosin can cause significant hypotension and syncope and should be initiated at bedtime with slow titration of dose.</p> <p>Praosin can cause more CNS adverse consequences and generally should be avoided.</p>	<ol style="list-style-type: none"> 1. Document supporting diagnoses for multiple antihypertensives 2. Monitor blood pressure and potential adverse consequences. 3. Suggest therapeutic alternative if possible. 4. If prazosin is continued, monitor blood pressure and potential adverse consequences.
ZJ	ACEIs/ARB's	Not listed in regulations	<p>Monitoring of serum potassium is necessary.</p> <p>May cause angioedema, persistent chronic cough, or worsen renal failure.</p> <p>Potential for life-threatening potassium concentrations when used in combination with potassium supplements, or potassium-sparing diuretics, including spironolactone.</p>	<ol style="list-style-type: none"> 1. Monitor serum potassium and creatinine. 2. Monitor for potential adverse consequences.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
ZK	Beta Blockers	Not listed in Regulations.	<p>May cause or exacerbate: bradycardia, dizziness, fatigue, depression, bronchospasm, cardiac decompensation (that may require adjusting dose in heart failure patients).</p> <p>May mask tachycardia associated with hypoglycemia.</p> <p>May exhibit increased effect or accumulation in individuals with hepatic impairment.</p>	1. Monitor for potential adverse consequences.
ZL	Calcium Channel Blockers	Not listed in regulations.	<p>May cause clinically significant constipation, peripheral edema, generalized aching, headache, muscle pain.</p> <p>Short acting nifedipine increases risk of cardiac complications and should not be prescribed.</p>	<p>1. Monitor for adverse consequences.</p> <p>2. Identify therapeutic alternative.</p>
ZM	Methyldopa	Alternate therapy for hypertension is preferred. Methyldopa may cause bradycardia and excessive sedation and may exacerbate depression in older patients.	Alternate therapy for hypertension is preferred. Methyldopa may cause bradycardia and excessive sedation and may exacerbate depression in older patients.	1. Recommend alternative therapy.
ZN	Digoxin	Doses should rarely exceed 0.125mg daily except when treating atrial arrhythmias exception: higher doses for use up to 7 days before facility would have to justify risk vs. benefit	<p>Indicated for only the following: CHF, AFIB, PSVT, or atrial flutter use with caution in patients with impaired renal function. Dosage in older patients should ordinarily not exceed 0.125mg/day except when used for atrial arrhythmia and ventricular rate.</p> <p>Close monitoring of both renal function and serum digoxin concentration.</p> <p>Adverse consequences may occur even with therapeutic concentrations.</p> <p>May interact with many other medications; may cause significant bradycardia, fatigue, nausea and vomiting, anorexia, weight loss, delirium, and cardiac arrhythmia.</p>	1. Monitor serum digoxin concentrations, renal function, potential adverse consequences and potential drug interactions.
ZO	Diuretics	Not listed in regulations.	May cause fluid and electrolyte imbalance, hypotension, precipitate or exacerbate urinary incontinence, falls.	<p>1. Monitor blood pressure and potential adverse consequences.</p> <p>2. Monitor electrolytes.</p>
ZP	Nitrates	Not listed in regulations.	May cause headache, dizziness, lightheadedness, faintness, orthostatic hypotension especially when initially started or when taken with other antihypertensive medications.	1. Monitor potential adverse consequences.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
ZQ	HMG-CoA Reductase Inhibitors (“Statins”)	Not included in old guidelines.	LFT Monitoring - prior to initiation of therapy, at 12 weeks following both initiation of therapy and any increase in dose, and periodically thereafter. Monitor for liver function impairment. Monitor for muscle pain, myopathy, and rhabdomyolysis, especially when used with other cholesterol-lowering agents.	<ol style="list-style-type: none"> 1. Monitor LFT and cholesterol panel before starting statin, 12 weeks after starting new statin order, and then every 6 months thereafter. 2. Monitor ALT and cholesterol panel 6 weeks after increase in statin dose and then every 6 months thereafter. 3. Monitor for signs and symptoms of liver toxicity. 4. After starting statin therapy or increasing statin dosage, monitor for any new muscle pain, myopathy, rhabdomyolysis, and kidney failure periodically. Consider obtaining a creatine kinase and/or creatine phosphokinase with any muscle weakness, pain, or signs and symptoms of rhabdomyolysis. Especially monitor for these side effects if using in combination with other cholesterol lowering medications (fibrates, niacin).
ZR	Cholestyramine	Not included in old guidelines.	May reduce absorption of certain medications which should be administered one hour before or four hours after cholestyramine (e.g. diuretics, beta blockers, corticosteroids, thyroid hormones, digoxin, valproic acid, NSAIDs, sulfonylureas and warfarin). Monitor for constipation, dyspepsia, nausea or vomiting, abdominal pain.	<ol style="list-style-type: none"> 1. Monitor for drug interactions and potential adverse consequences. 2. Monitor appropriate drug administration times.
ZS	Fibrates	Not included in old guidelines	Obtain periodic LFTs and a CBC prior to and after initiation of fibrates.	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
ZT	Niacin	Not included in old guidelines	Periodic LFTs and periodic serum glucose. Monitor for flushing, and caution when used in patients with active gallbladder disease and gout.	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
ZU	<u>Cognitive Enhancers</u> Cholinesterase Inhibitors	Not included in old guidelines	Assessment for use in advanced Alzheimer stages. Monitor for cardiac conduction, monitor for insomnia, dizziness, nausea and vomiting, diarrhea, anorexia, weight loss. Use with caution in individuals with severe asthma or COPD.	<ol style="list-style-type: none"> 1. Document that drug therapy is indicated. 2. Monitor for potential adverse consequences.
ZV	Memantine	Not included in old guidelines	Assessment for use in advanced Alzheimer stages Monitor for restlessness, distress, dizziness, somnolence, HTN, headache, hallucinations, or increased confusion.	<ol style="list-style-type: none"> 1. Document that drug therapy is indicated. 2. Monitor for potential adverse consequences.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
ZW	<u>Cough, Cold and Allergy Medications</u>	Not included in old guidelines	Short term use (less than 14 days) unless documented evidence to continue.	<ol style="list-style-type: none"> 1. Monitor duration. 2. If continued beyond 14 days, document rationale for continued need.
ZX	H-1 Antihistamine Blockers	May worsen BPH, Monitor for anticholinergic side effects	<p>Use non-sedating antihistamines instead which may have less anticholinergic side effects. Use topical antihistamines for allergic reactions involving the skin.</p> <p>Use the smallest possible doses for shortest duration, especially if taking other medications with anticholinergic properties.</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
ZY	Oral Decongestants	Not included in old guidelines	<p>Monitor for dizziness, nervousness, insomnia, palpitations, urinary retention, elevated blood pressure.</p> <p>Use with caution in patients with HTN and monitor blood pressure regularly.</p> <p>Use with caution in patients with insomnia (may worsen insomnia).</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
ZZ	<u>GI Medications</u> Phenothiazine-related Antiemetics (prochlorperazine, promethazine)		<p>Use with caution in individuals with Parkinson's disease, narrow-angle glaucoma, BPH, seizure disorder.</p> <p>Monitor for sedation, dizziness, drowsiness, postural hypotension, neuroleptic malignant syndrome. Monitor with patients with seizure disorders (may lower seizure threshold), Monitor for anticholinergic side effects, Monitor for EPS (especially if used with other drugs that may cause EPS). May alter cardiac conduction or induce arrhythmias.</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
YA	Trimethobenzamide	Not included in old guidelines	Monitor for EPS, lethargy, sedation, and confusion.	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
YB	Metoclopramide	May lower seizure threshold. May cause EPS.	<p>Not first line agent for GERD. Consider using H2 antagonists or PPIs for GERD. If used for diabetic gastroparesis document risks vs. benefits.</p> <p>May lower seizure threshold - use with caution in patients with seizure disorder.</p> <p>Use with caution in patients with Parkinson's Disease - may exacerbate symptoms.</p> <p>Monitor for restlessness, drowsiness, insomnia, depression, distress, anorexia, EPS, seizures. Always monitor the risk vs. benefit when using metoclopramide.</p>	<ol style="list-style-type: none"> 1. Identify alternative therapy. 2. If continued, monitor for potential adverse consequences. 3. Administer AIMS/DISCUS.

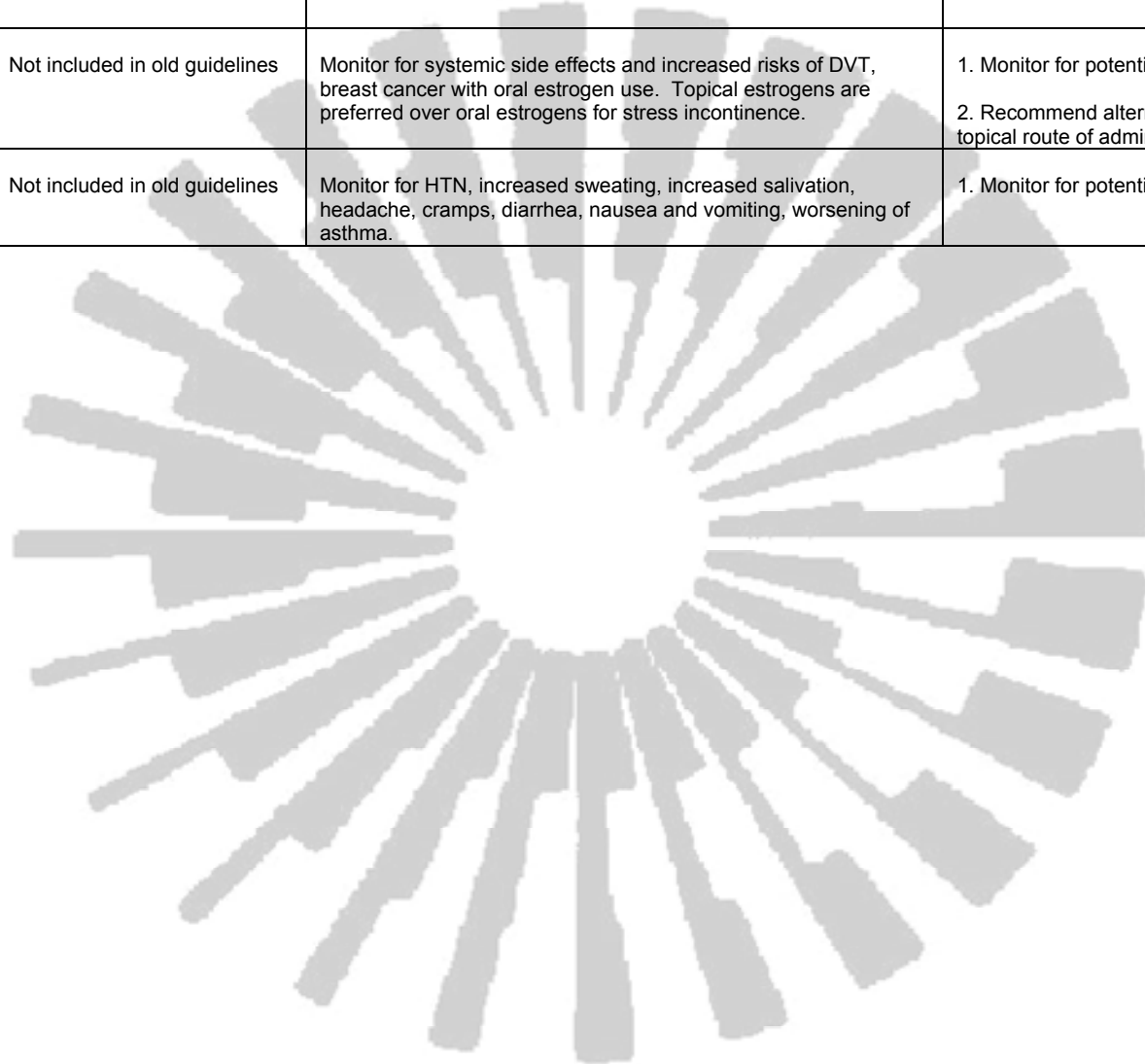
	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
YC	Proton Pump Inhibitors and H2 Antagonists	Not included in old guidelines	<p>If used to treat or prevent NSAID induced gastritis or esophagitis, documentation should exist that other less harmful analgesics have been tried or were not indicated.</p> <p>Should not be used for more than 12 weeks without proper documentation.</p> <p>Dose H2 Antagonists based on renal function.</p> <p>Monitor for headache, nausea, vomiting, flatulence, dysphagia, abdominal pain, diarrhea, or other GI symptoms. PPIs may increase risk of C. difficile. H2 Antagonists may cause confusion. Cimetidine should not be used in the elderly, due to drug interactions.</p>	<ol style="list-style-type: none"> 1. If continued beyond 12 weeks, document continued need. 2. Verify renal-adjusted appropriate dose. 3. Monitor for potential adverse consequences. 4. Recommend alternative therapy for cimetidine.
YD	<u>Glucocorticoids</u> (all except topical or inhaled dosage forms)	Not included in old guidelines	Proper documentation and monitoring of adverse consequences such as hyperglycemia, psychosis, edema, insomnia, HTN, osteoporosis, mood lability, or depression.	
YE	<u>Erythropoiesis Stimulants</u> (darbepoetin, erythropoietin)	Not included in old guidelines	<p>Monitor blood pressure, baseline serum iron or ferritin level, CBC, Hgb or HCT based on manufacturer's recommendations.</p> <p>Proper indication needed. Monitor blood pressure in patients with HTN. Monitor for polycythemia and thrombotic events with chronic duration or high doses.</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor laboratory parameters and document diagnosis.
YF	<u>Iron</u>	Not included in old guidelines	<p>Use for greater than 2 months should be clinically documented. Administration of more than once daily for greater than 1 week should be documented.</p> <p>Monitor baseline serum iron or ferritin concentration. Monitor periodic CBC or Hgb/HCT. Monitor for constipation, dyspepsia.</p>	<ol style="list-style-type: none"> 1. If full iron replacement doses are indicated, document continued need and rationale for dose. 2. Monitor for potential adverse consequences. Recommend laxative therapy if appropriate.
YG	<u>Laxatives</u>	Not included in old guidelines	Monitor for flatulence, bloating, abdominal pain. Use caution with bulk forming laxatives and stool softeners for the possibility of bowel obstruction (stress giving with appropriate fluids).	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor administration technique. 3. Ensure adequate fluid intake and exercise as tolerated.
YH	<u>Muscle Relaxants</u>	Not included in old guidelines	Monitor for anticholinergic effects. Caution about abrupt cessation of muscle relaxants which may cause or predispose individuals to seizures or hallucinations	<ol style="list-style-type: none"> 1. Monitor for sedation, weakness and anticholinergic side effects.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
YI	<u>Appetite Stimulants</u> (megesterol acetate, oxandrolone, dronabinol)	Not included in old guidelines	<p>Must assess underlying correctable causes of anorexia and weight loss before use. Risk vs. benefit must be assessed. Appetite and weight should be monitored monthly and agent should be discontinued if no improvement.</p> <p>Monitor for fluid retention, adrenal suppression, and symptoms of adrenal insufficiency with megesterol.</p> <p>Monitor for tachycardia, orthostatic hypotension, dizziness, dysphoria, impaired cognition, and falls with dronabinol use.</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences.
YJ	<u>Bisphosphonates</u>	Not included in old guidelines	<p>These medications are taken 30 minutes before 1st food, beverage, or medication of the day with 8 oz water only. Do not lie down at least 30 minutes after administration. Remain upright at least 30 minutes after administration.</p> <p>Monitor for gastrointestinal complications, including esophageal or gastric erosion. Monitor GI side effects especially when using with oral corticosteroids, aspirin or other NSAIDs.</p>	<ol style="list-style-type: none"> 1. Assure appropriate drug administration techniques. 2. Ensure adequate intake of calcium and vitamin D. 3. Monitor for potential adverse consequences. 4. Monitor renal function.
YK	<u>All Platelet Inhibitors</u> (dipyridamole, Aggrenox, aspirin, clopidogrel)	May cause bleeding in individuals receiving concomitant anticoagulants	<p>Monitor for thrombocytopenia and increase risk of bleeding, headache, dizziness, and vomiting. Caution when prescribing warfarin or NSAIDs with antiplatelet agent, which may increase risk of bleeding. NSAIDs may attenuate the antiplatelet effect of aspirin.</p>	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor for potential drug interactions. 3. If possible, discontinue interfering medication or document rational for continued need.
YL	<u>Ticlopidine</u>	No more effective than aspirin and considerably more toxic.	<p>Should only be used if patient cannot tolerate aspirin or other platelet inhibitors.</p> <p>Use in elderly not recommended due to toxic side effects. Monitor for hematologic side effects such as neutropenia (i.e. CBC). Monitor for nausea, vomiting and diarrhea.</p>	<ol style="list-style-type: none"> 1. Identify alternative therapy. 2. If continued, monitor for potential adverse consequences.
YM	<u>Theophylline</u>	Not included in old guidelines	<p>Caution in concomitant use with various antibiotics, seizure medications and cardiac medications as may cause drug interactions.</p> <p>Monitor for symptoms of theophylline toxicity such as arrhythmias, seizures, GI upset, diarrhea, nausea/vomiting, abdominal pain, nervousness, headache, insomnia, distress, dizziness, muscle cramp and tremor.</p> <p>Monitor theophylline serum concentrations at least every 6 months.</p>	<ol style="list-style-type: none"> 1. Monitor for potential drug interactions. 2. Monitor for potential adverse consequences. 3. Recommend alternative therapy where appropriate. 4. Monitor serum theophylline concentrations.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
YN	<u>Inhaled Anticholinergics</u> (ipratropium, tiotropium)	Not included in old guidelines	Monitor for dry mouth	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor for proper labeling and administration.
YO	<u>Inhaled Beta 2 Agonists</u> (albuterol, formoterol, pirbuterol, salmeterol)	Not included in old guidelines	Monitor or restlessness, increased heart rate, anxiety.	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor for proper administration.
YP	<u>Inhaled Corticosteroids</u>	Not included in old guidelines	Monitor for throat irritation and oral candidiasis. Must rinse mouth after use.	<ol style="list-style-type: none"> 1. Monitor for potential adverse consequences. 2. Monitor for proper administration.
YQ	<u>Sedative/Hypnotics</u>	Proper indication; must try non pharmacological methods before sedative/hypnotic use; caution with long-acting benzodiazepines and chloral hydrate with COPD; Caution with sedating antihistamines with BPH; dose limitation in elderly.	Most cases of insomnia are associated with underlying conditions such as psychiatric disorders, cardiopulmonary disorders, urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome. Proper indication of insomnia must be documented. Must try non-pharmacologic methods to treat insomnia before sedative/hypnotic.	<ol style="list-style-type: none"> 1. Document initiation and maintenance of non-pharmacologic therapy. 2. Assure documentation of appropriate indication for drug therapy. 3. Evaluate duration of therapy.
	(Benzodiazepines, non-benzodiazepines, melatonin receptor agonists, chloral hydrate, sedating antidepressants (trazodone), sedating antihistamines (hydroxyzine)	<p>Dosage</p> <p>alprazolam 0.25mg chloral hydrate 500mg diphenhydramine 25mg estazolam 0.5mg Not included flurazepam 15mg hydroxyzine 50mg lorazepam 1mg oxazepam 15mg Not included Not included temazepam 7.5mg triazolam 0.125mg Not included zolpidem 5mg</p>	<p>Dosage</p> <p>Not included chloral hydrate* 500mg diphenhydramine* 25mg estazolam 0.5mg eszopiclone 1mg flurazepam* 15mg hydroxyzine* 50mg lorazepam 1mg oxazepam 15mg quazepam* 7.5mg ramelteon 8mg temazepam 15mg- note new dose triazolam* 0.125mg zaleplon 5mg zolpidem 5mg</p> <p>*not considered medications of choice for the management of insomnia in older individuals</p>	<ol style="list-style-type: none"> 1. Recommend alternative therapy where appropriate.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
	<u>Sedative/Hypnotics</u> (continued)	Avoid daily use of the drug for longer than 10 continuous days unless an attempt at a gradual dose reduction is unsuccessful.	For as long as the resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use, the facility should attempt to taper the medication at least quarterly unless clinically contraindicated. For these medications, clinically contraindicated means that the physician has documented the clinical rationale for why any additional attempted tapering would be likely to impair the resident's function or cause psychiatric instability or the resident's target symptoms returned or worsened after the most recent GDR.	1. Monitor for potential adverse consequences.
YS	<u>Barbiturates</u>	Caution with use in COPD. Barbiturates should not be used without trial of other sedative/hypnotics or anti-anxiety medications (exception - use for seizure disorder)	For as long as the resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use, the facility should attempt to taper the medication at least quarterly unless clinically contraindicated. For these medications, clinically contraindicated means that the physician has documented the clinical rationale for why any additional attempted tapering would be likely to impair the resident's function or cause psychiatric instability or the resident's target symptoms returned or worsened after the most recent GDR. Monitor for hypotension, dizziness, lightheadedness, "hangover" effect, drowsiness, confusion, mental depression, unusual excitement, nervousness, headache, insomnia, nightmares, hallucinations and falls	1. Barbiturates not recommended in the elderly for sleep or to treat anxiety disorder. 2. Recommend appropriate alternative therapy. 3. Monitor for potential adverse consequences. 4. Monitor for drug interactions.
YT	<u>Thyroid Medications</u>	Not included in old guidelines	Monitoring of adverse consequences. Start low and go slow with dosing. Assessment of thyroid function prior to and periodically, e.g. (TSH, T4, and T3).	1. Monitor for drug interactions. 2. Monitor for signs and symptoms of hypo or hyperthyroidism. 3. Monitor relevant laboratory parameters.
YU	<u>Urinary Incontinence Medications</u> Anticholinergics - darifenacin, oxybutynin, tolterodine, trospium	May worsen BPH. Monitor for anticholinergic side effects	Monitor for anticholinergic side effects. Assessment of cause of urinary incontinence before or soon after use.	1. Monitor for potential adverse consequences. 2. Monitor for potential drug interactions.
YV	TCA (desipramine, imipramine)	May worsen BPH. Monitor for anticholinergic side effects, Monitor in patients with cardiac arrhythmias	Same	1. Monitor for potential adverse consequences.

	Medication	F329 Old Regulations	F329 New Regulations	Suggested Monitoring Guidance for SOM Issues and Concerns
YW	Stress incontinence (alpha adrenergic agonists - pseudoephedrine)	Not included in old guidelines	Ongoing assessment of effects of medication and symptoms of urinary incontinence.	1. Monitor for potential adverse consequences.
YX	Mixed incontinence (estrogen replacement agents)	Not included in old guidelines	Monitor for systemic side effects and increased risks of DVT, breast cancer with oral estrogen use. Topical estrogens are preferred over oral estrogens for stress incontinence.	1. Monitor for potential adverse consequences. 2. Recommend alternative therapy such as vaginal creams or topical route of administration.
YY	Overflow incontinence (bethanechol)	Not included in old guidelines	Monitor for HTN, increased sweating, increased salivation, headache, cramps, diarrhea, nausea and vomiting, worsening of asthma.	1. Monitor for potential adverse consequences.



Glossary of Abbreviations	
A1c	glycosylated hemoglobin
ACEIs	angiotensin converting enzyme inhibitors
AFIB	atrial fibrillation
ALT	alanine aminotransferase
ARB	angiotensin receptor blocker
ASA	aspirin
BPH	benign prostatic hyperplasia
CBCs	complete blood counts
CHF	congestive heart failure
CNS	central nervous system
COMT	catechol -O-methyl-transferase
COPD	chronic obstructive pulmonary disease
COX-Is	cyclo-oxygenase receptor II inhibitors
CVA	cerebrovascular accident, i.e. stroke
DVT	deep vein thrombosis
EPS	extrapyramidal symptoms
GDR	gradual dose reduction
GERD	gastroesophageal reflux disease
GFR	glomerular filtration rate
GI	gastrointestinal
H2 Antagonists	histamine-2 receptor antagonist
HCT	hematocrit
Hgb	hemoglobin
HTN	hypertension
INR	international normalized ratio
LFTs	liver function tests
MAO	monoaminoxidase
NOS	not otherwise specified
NSAIDs	nonsteroidal antiinflammatory drugs
QTc	corrected Q-T interval of the electrophysiologic depolarization of the myocardium
OCD	obsessive compulsive disorder
OMS	organic mental syndrome
PPIs	proton pump inhibitors
PT	prothrombin time
PSVT	paroxysmal supraventricular tachycardia
SIADH	syndrome of inappropriate antidiuretic hormone secretion
SSRIs	selective serotonin reuptake inhibitors
T3	triiodothyronine
T4	thyroxine
TG	triglycerides
TSH	thyroid stimulating hormone
UTIs	urinary tract infections