

Ohio Board of Nursing www.nursing.ohio.gov

17 South High Street, Suite 400 • Columbus, Ohio 43215-7410 • (614) 466-3947

New Drug Indications / Warnings January 2010

(New Drug Indications/Black Box Warnings: FDA

Generic Name	Trade Name	Indication(s)	CPG Action/Date
	Septemb	er 2009	
Zolendronic Acid Injection Formulary Pg. 8	Zometa, Reclast	Endocrine and Metabolic Agents: Biphosphonates. New indication for prevention of osteoporosis in postmenopausal women.	Current: Zometa- CTP holder MAY NOT prescribe. Reclast – Physician Initiated/Physician Consult. 01/14/10 Change Zometa and Reclast to Physician Initiated / Physician Consult
Certolizumab Pegol Injection Formulary Pg. 22	Cimzia	Biologic and Immunologic Agents: Immunologic Agents: Immunomodulators. New indication for rheumatoid arthritis.	Current: Physician Initiated/ Physician Consult for CTP hematology /oncology CTP holders only. CTP holder MAY NOT prescribe for all others. 01/14/10 Change to Physician Initiated / Physician Consult for all CTP holders.
	Octobe	r 2009	
Metoprolol Tartrate and Succinate oral and Tartrate Injection Formulary Pg. 12	Metoprolol Tartrate, Lopressor, Metoprolol Succinate, Toprol XL	Cardiovasculars: Antiadrenergics/ Sympatholytics: Beta- Adrenergic Blocking Agents. New black box warning indicating that following abrupt cessation of therapy with certain beta- blocking agents exacerbations of angina pectoris and in some cases myocardial	Current: PO- CTP Holder MAY Prescribe. IV- Acute Care CTP holders may prescribe. Non-acute care CTP holders per institution protocol in monitored units and as stated in the standard care arrangement. See

		infarction have occurred.	footnote #1.
Timolol Maleate Oral Formulary Pg. 12 Nadolol Oral Formulary Pg. 12	Timolol Maleate, Blocadren Nadolol, Corgard	Cardiovasculars: Antiadrenergics/ Sympatholytics: Beta- Adrenergic Blocking Agents. New black box warning regarding exacerbation of ischemic heart disease following abrupt withdrawal of drug. Cardiovasculars: Antiadrenergics/ Sympatholytics: Beta- Adrenergic Blocking Agents. New black box warning regarding exacerbation of ischemic heart disease following abrupt	01/14/10 No Change Current: PO- CTP Holder MAY Prescribe. 01/14/10 No Change Current: PO - CTP Holder MAY Prescribe. 01/14/10 No Change
Propranolol Hydrochloride Oral and Injection Formulary Pg. 12	Propranolol Hydrochloride, Inderal LA, InnoPran XL, Propranolol Intensol, Inderal	withdrawal of drug. Cardiovasculars: Antiadrenergics/ Sympatholytics: Beta- Adrenergic Blocking Agents. New black box warning regarding angina pectoris and in some cases myocardial infarction following abrupt withdrawal of propranolol.	Current: PO CTP Holder MAY Prescribe. IV - Acute Care CTP holders may prescribe. Non-acute care CTP holders per institution protocol in monitored units and as stated in the standard care arrangement. See footnote #1.
Paliperidone Oral Formulary Pg.16	Invega	Central Nervous System Agents: Antipsychotic drugs: Benzisoxazole Derivatives. New indication for schizoaffective disorder.	01/14/10 No Change Current: Psych CTP holder MAY prescribe. Initial 90 day review. CTP holder other than psych Physician Initiated/Physician Consult. Initial 90 day review.

Sodium Phosphate Oral Formulary Pg. 19	Visicol, OsmoPrep	<i>Gastrointestinal</i> <i>Agents: Laxatives:</i> <i>Bowel Evacuants.</i> New black box warning regarding rare but serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products for colon	01/14/10 Change to CTP holder may prescribe for all prescribers. Eliminate initial 90 day review requirement. Current: CTP holder MAY prescribe. 01/14/10 No Change
		cleansing prior to	
	Novemb	colonoscopy.	
Atomolol Orol			Cumont
Atenolol Oral Formulary Pg. 12	Atenolol, Tenormin	Cardiovasculars: Antiadrenergics/ Sympatholytics: Beta- Adrenergic Blocking Agents. New black box warning advising against abrupt cessation of drug. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in patients with angina following abrupt discontinuation of therapy with beta- blockers.	Current: CTP holder MAY prescribe 01/14/10 No Change
Sympathomimetics		Respiratory Agents:	Current:
Formulary Pg. 13		Bronchodilators: Sympathomimetics. New black box warning indicating that long- acting beta-2 agonists may increase the risk of	CTP holder MAY prescribe 01/14/10 No Change
		asthma-related death.	
Risperidone Injection Formulary Pg.16	Resperidone, Resperdal, Risperdal M-Tab	Central Nervous System Agents: Antipsychotic Agents: Benzisoxazole	Current: Psych CTP holder MAY prescribe. Initial 90 day

Risperidone Injection	Resperidone,	Central Nervous	Current:
Formerilam, Do 16	Resperdal, Risperdal M-Tab	System Agents:	Psych CTP holder
Formulary Pg.16	M-Tab	Antipsychotic Agents: Benzisoxazole	MAY prescribe.
			Initial 90 day review.
		Derivatives. New	review.
		indication for bipolar disorder.	CTP holder other
		uisorder.	than psych
			Physician
			Initiated/Physician
			Consult. Initial 90
			day review.
			day review.
			01/14/10
			Change to CTP
			holder may
			prescribe.
			Eliminate initial 90
			day review
			requirement.
			r oquin onnoniu
Tigecycline Injection	Tygacil	Anti-Infectives,	Current: Not listed
		Systemic:	
Formulary Pg. 20		<i>Glycylclyclines</i> . New	01/14/10 Physician
		indication for	Initiated / Physician
		community-acquired	Consult
		bacterial pneumonia.	
Lapatinib Ditosylate	Tykerb	Antineoplastic Agents:	Current:
Oral		Tyrosine Kinase	CTP holder MAY
		Inhibitors. New black	NOT prescribe.
Formulary Pg.		box warning regarding	
		hepatoxicity.	01/14/10
			No Change
	Decemb	er 2009	
NONE			
	1		



Ohio Board of Nursing www.nursing.ohio.gov

17 South High Street, Suite 400 • Columbus, Ohio 43215-7410 • (614) 466-3947

New Drugs January 2010

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date	
September 2009				
Ferumoxytol Injection Formulary Page 5	Feraheme	Nutritients & Nutritional Agents: Trace Elements: Iron. Indication for iron deficiency anemia.	01/14/10 Physician Initiated / Physician Consult	
Prasugrel Hydrochloride Oral Formulary Pg. 6	Effient	Hematologic Agents: Antiplatelet Agents: Aggregation Inhibitors. Indication for acute coronary syndrome	01/14/10 Physician Initiated / Physician Consult	
Dronedarone Oral Formulary Pg. 11	Multaq	Cardiovasculars: Antiarrhythmic Agents. Indication for paroxysmal or persistent atrial fibrillation or paroxysmal or persistent atrial flutter.	01/14/10 CTP may prescribe	
Tapentadol Hydrochloride Oral Formulary Pg. 15	Nucynta	Central Nervous System Agents: Opioid Analgesics. Indication for acute pain.	01/14/10 CTP may prescribe	
Canakinumab Injection Formulary Pg. 22	Ilaris	Biologic and Immunological Agents: Immunologic Agents: Immunomodulators. Indication for cyropyrin- associated periodic syndromes.	01/14/10 Physician Initiated / Physician Consult	
	Octobe	r 2009		
Pitavastatin Oral Formulary Pg. 12	Livalo	Cardiovasculars: Antihyperlipidemic Agents: HMG-CoA Reductase Inhibitors. Indication for primary hyperlipidemia and mixed dyslipidemia.	01/14/10 CTP may prescribe	
Asesapine Oral Formulary Pg. 16	Saphris	Central Nervous System Agents: Antipsychotic Drugs: Dibenzapine Derivatives. Indication Schizophrenia and bipolar disorder.	01/14/10 CTP holder may prescribe	

November 2009				
Influenza A (H1N1)	Influenza A (H1N1)	Biologic and	01/14/10 CTP	
Vaccine Injection and	2009 Monovalent	Immunologic Agents:	holder may	
Intranasal	Vaccine	Agents for Active	prescribe	
		Immunization:		
Formulary Pg. 22		Vaccines, Viral.		
		Indication for H1N1		
		influenza.		
		per 2009		
Saxagliptin	Onglyza	Endocrine and	01/14/10	
Hydrochloride Oral		Metabolic Agents:	CTP may prescribe	
		Antidiabetic Agents:		
Formulary Pg. 9		Dipeptidyl Peptidase-4		
		Inhibitor. Indication for		
		Type 2 diabetes mellitus.		
Telavancin	Vibativ	Anti-infectives,	01/14/10	
Hydrochloride		systemic:	Physician Initiated /	
Injection		Lipoglycopeptides.	Physician Consult	
		Indication for		
Formulary Pg. 20-21		complicated skin and		
		skin structure infections.		
Ustekinumab	Stelara	Biologic and	01/14/10	
Injection		Immunologic Agents:	Physician Initiated /	
		Immunologic Agents:	Physician Consult	
Formulary Pg. 22		Immunomodulators.		
		Indication for plaque		
		psoriasis.		
Bepotastine Besilate	Bepreve	Ophthalmic Agents:	01/14/10	
Ophthalmic		Mast Cell Stabilizers.	CTP may prescribe	
		Indication for allergic		
Formulary Pg. 23	Dalat a	conjunctivitis.		
Pralatrexate Injection	Folotyn	Antineoplastic Agents:	01/14/10 CTD MAX NOT	
		Antimetabolites: Folic	CTP MAY NOT	
Formulary Pg. 24		Acid Antagonists.	prescribe	
		Indication for peripheral T-cell lyphoma.		
Pazopanib	Votrient	**	01/14/10	
Hydrochloride Oral	votrient	Antineoplastic Agents:	01/14/10 CTP MAY NOT	
nyurocinoriue Oral		<i>Tyrosine Kinase</i> <i>Inhibitors.</i> Indication for	prescribe	
Formulary Pg. 24		renal cell carcinoma.	preseribe	
ronnuary rg. 24				



Ohio Board of Nursing www.nursing.ohio.gov

17 South High Street, Suite 400 • Columbus, Ohio 43215-7410 • (614) 466-3947

Formulary Revision Request January 2010

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
Formulary Review Revision Request from Tonia Lower CNP			
Zoledronic Acid Formulary Pg. 8	Zometa	Endocrine and Metabolic Agents: Biphosphonates. Indication for hypercalcemia of malignancy, multiple myeloma and bone metastases from solid tumors. Requesting CTP holder may prescribe.	Current: CTP holder MAY NOT prescribe. 01/14/10 Change to Physician Initiated / Physician Consult
Pamidronate Formulary Pg. 8	Aredia	Endocrine and Metabolic Agents: Biphosphonates. Indication for hypercalcemia of malignancy, Paget disease, osteolytic bone metasteses of breast cancer and osteolytic lesions of multiple myeloma. Requesting CTP holder may prescribe.	Current: CTP holder MAY NOT prescribe. 01/14/10 Change to Physician Initiated / Physician Consult
Formulary Review R	Revision Request from	Sarah Otto CNP, Ying Y	ang CNP
Isotretinoin Formulary Pg. 23	Accutane	Dermatologic Agents: Retinoids: First Generation Retinoids. Indication for severe recalcitrant nodular acne. Requesting Physician Initiated.	Current: CTP holder MAY NOT prescribe. 01/14/10 CTP holder MAY NOT prescribe. To be discussed at May 2010 CPG meeting.

Formulary Review Revision Request from Lisa Miller CNP			
Isotretinoin	Accutane, Claravis,	Dermatologic Agents:	Current: CTP holder
	Sotret, Amnesteem	Retinoids: First	MAY NOT
Formulary Pg. 23		Generation Retinoids.	Prescribe
		Indication for severe	
		recalcitrant nodular	01/14/10
		acne.	CTP holder MAY
			NOT prescribe. To
		Requesting Physician	be discussed at May
		Initiated.	2010 CPG meeting.
			_